

MEDICAL RADIATION: AN OVERVIEW OF THE ISSUES

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED ELEVENTH CONGRESS SECOND SESSION

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MEDICAL RADIATION: AN OVERVIEW OF THE ISSUES

FRIDAY, FEBRUARY 26, 2010

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:03 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. [Chairman of the Subcommittee] presiding.

Members present: Representatives Pallone, Eshoo, Green, Schakowsky, Barrow, Christensen, Castor, Sutton, Waxman (ex officio), Whitfield, Shimkus, Myrick and Gingrey.

Staff present: Steve Cha, Professional Staffer; Ruth Katz, Chief Public Health Counsel; Elana Leventhal, Professional Staff; Eric Flamm, FDA Detailee; Alvin Banks, Special Assistant; and Chad Grant, Legislative Analyst.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. The Subcommittee is called to order and today we are meeting to discuss the topic medical radiation and the overview of the issues.

By now, I am sure many of you have read or at least heard of the New York Times article series on medical radiation errors. The patient's stories highlighted in those articles are heartrending and they have raised huge concerns and questions for me as well as for many of my fellow members in the House of Representatives. I actually was just reading now today's New York Times where there is a front page story about a group, a radiation oncology group in Melbourne, Florida that raised a lot of the issues. I mean the article today raised many of the issues that we are going to bring out today but particularly disturbing was the fact that this group practice apparently had the physicians who were not present, who were actually overseas and were billing on the assumption that those physicians were present and I guess had to be present under the rules and yet they were not. So those are some of the problems that are highlighted in today's New York Times and have been in a whole series.

I want to start, however, by saying that medical radiation undoubtedly saves lives. It has reshaped the world of diagnostics and has offered patients less invasive alternatives for treating complex and life-threatening conditions. Personally, I don't want to express

any concern that in having this hearing that we are sending the message that medical radiation is bad. I want to assure you that that is not the case. It is important that patients do not stop going to their scheduled treatments or getting their CAT scans when they need them, and we are not here today to make the statement that medical radiation should not be used.

But we are here today to learn more about the field and to examine what the driving factors are when things go wrong. Due to the dangerous nature of these technologies, when things do go wrong the effects on patients are horrendous. As mentioned, the benefits that we as a society have gained from these advances are enormous but we often forget the fact that we are still dealing with something that is toxic to the human body. When it is delivered correctly, a single CAT scan can deliver as much radiation as 300 chest x-rays. With the operating technology as powerful and dangerous as this it is even more crucial that quality and safety are always front and center, but tragically, as highlighted in these New York Times articles, this is not always the case. A procedure with such a small margin of error should be stringently overseen and monitored but these critical steps appear to be lacking in many cases.

With all the advances the industry has made, these technologies have become more complex and complicated to operate. It is shocking to me that in many States individuals who operate these devices do not need to be licensed and are therefore not regulated at all in terms of education and expertise. Even in States where there are licensing requirements, the requirements to report errors and the penalties for making errors are basically nonexistent or not enforced. Now as a result, we have no idea how often these errors occur and have no good data on where the weaknesses in the system truly are.

I understand Mr. Barrow has legislation that deals with training and possibly accreditation as well so, you know, obviously when we have these hearings we are looking at the possibility of legislation and Mr. Barrow's is certainly one of those that we would be looking at. I think part of the problem could be the fact that no single agency has authority over the entire spectrum of issues related to medical radiation and because of this things are more likely to fall through the cracks and I am eager to hear from our witnesses today about this and what problems it presents.

In addition to the lack of oversight from a regulatory perspective, there also appears to be very little guidance to physicians on the appropriateness of use of these technologies especially with respect to radiation dosage and lifetime exposure of radiation. One of our witnesses today will go into more detail on this issue but for example, dosing for the same CAT scan can vary by huge amounts between and within facilities. In addition, there are questions as to the appropriateness of use of these scans.

I know from personal experience that health care providers are very quick to order yet another CAT scan without talking to patients about the health risks let alone the cumulative effects of multiple scans. When I say my own experience is from my mom. My mom passed away last December and the reality—not this December but the previous one, and I remember she had pancreatic

cancer that when we were going around to different hospitals and we ended up I think at four different hospitals, every time I would go to a new hospital I would bring the scan with me, you know, the disc I guess. And I would give it to them and they would say well we can't use that and I would say well why, and they would say well, you know, our machines don't operate that way of maybe it is a good idea to have another one and I wasn't concerned. I mean frankly I wasn't addressing it from a cost perspective although that is a big factor but I was worried about the health implications and, you know, frankly most no one said to me that there was a problem. It was always like oh that is not a problem, you know, she can have it done again and nobody actually would use the previous one. I was never able to get them to use the disc that I had brought with me. They always had a reason why they couldn't use it and maybe there was a good reason but it just seems that maybe the lack of interoperability or, you know, one of those things that needs to be addressed.

Many in Congress have questioned the overuse of medical imaging but for the most part those conversations has centered on cost implications. I have to wonder though if there are not also health implications as well and I am eager to hear from our witnesses today about the issue and what is being done to study the long term cumulative effects of medical radiation.

Our witnesses today are all intimately familiar with these types of technologies, the possibilities they hold and the dangers they can present and I would like to welcome especially Ken Mizrach who is—where is Ken? Oh he is on the next panel I guess, who has traveled here from my home State of New Jersey and also Mr. Parks, whose son's story was featured in one of the New York Times articles, and we appreciate your taking the time to speak to the committee on this very important issue, and I think we are going to have some interesting conversation.

Before I recognize Mr. Whitfield though I did want to say that, you know, just reading today's New York Times article there are so many different factors here. You know, how much radiation, what type of technologies are used, whether we should have doctors present, how long they should be present, whether they should be nearby or there the whole time, and it is a very complex issue and I don't need to be simplistic about it but we should also get to the bottom of it. So with that, I will recognize my colleague from Kentucky, Mr. Whitfield.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Well, thank you, Chairman Pallone, and I also want to thank the witnesses for being here today to help educate us on this particularly important subject matter.

Medical radiation involves both radiation therapy and medical imaging. The medical community uses radiation therapy to treat cancerous tumors including brain cancer, breast cancer, lung cancer and prostate cancer just to name a few. They use medical imaging like CT scans and mammograms to find those tumors and identify other problems. It is clear that the overwhelming majority of

Americans who receive radiation therapy and medical imaging benefit greatly and thousands of lives are saved each year because of these treatments and procedures.

This hearing will also however focus in part on tragic events associated with radiation therapy. These events raise legitimate questions that we need to explore and my hope is that the members of the committee and the public will listen to the witnesses who are experts in this field and not proceed with preconceived notions. We must examine the issues associated with radiation therapy and medical imaging and if there are problems to be addressed we need to work with the manufacturers and the health care providers to do so. However, as we examine these issues it is important that no one comes away from this hearing thinking radiation therapy and medical imaging are too dangerous to use because too many lives are at stake.

I am particularly interested to hear from the manufacturers how these lifesaving technique devices work. I am also interested in hearing from the various provider groups on the training associated with operating these complex devices and how the different professional societies develop criteria so these devices can be operated safely. Radiation treatment is a complex issue and so we welcome the witnesses here today and are excited that you can help educate us on what if anything and what steps we need to take.

And I would yield back the balance of my time.

[The prepared statement of Mr. Whitfield follows:]

STATEMENT OF THE HONORABLE ED WHITFIELD

COMMITTEE ON ENERGY AND COMMERCE

HEALTH SUBCOMMITTEE HEARING:
MEDICAL RADIATION: AN OVERVIEW OF THE ISSUES
February 26, 2010

Thank you, Mr. Chairman for holding this hearing. I also want to thank our distinguished witnesses for coming here today to educate the Committee on this important topic.

Medical radiation involves both radiation therapy and medical imaging. The medical community uses radiation therapy to treat cancerous tumors, including brain cancer, breast cancer, lung cancer, and prostate cancer, just to name a few. They use medical imaging, like CT scans and mammograms, to find those tumors and identify other problems. It is clear that the overwhelming majority of

Americans who receive radiation therapy and medical imaging benefit greatly, and thousands of lives are saved each year because of these treatments and procedures.

This hearing will focus in part on tragic events associated with radiation therapy. These events raise legitimate questions that we need to explore. My hope is that the Members of the Committee and the public will listen to the witnesses without preconceptions. We must examine the issues associated with radiation therapy and medical imaging, and if there are problems to be addressed, we need to work with the manufacturers and providers to do so. However, as we examine these issues, it is important that no one comes away from this hearing thinking radiation therapy and medical imaging are not safe. Too many lives are at stake.

As an engineer, I am particularly interested to hear from the manufacturers how these life-saving devices work. I am also interested in hearing from the various provider groups on the training associated with operating these devices and how the different professional societies develop criteria so these devices are operated safely.

These are complex issues because there are so many moving parts, both literally and figuratively. I look forward to listening to the testimony of our witnesses and learning more about this important topic. I yield back.

Mr. PALLONE. Thank you.

The gentlewoman from Ohio, Ms. Sutton, is next for an opening.

**OPENING STATEMENT OF HON. BETTY SUTTON, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO**

Ms. SUTTON. Thank you, Mr. Chairman, and I appreciate you holding this hearing today. It is an important and complex issue that deserves our attention.

All of us know someone whose life has been saved by medical radiation whether a tumor was discovered with a CT scan and treated before it grew into something unmanageable or whether someone we love beat prostate cancer through the help of radiological seeds. There is no doubt that medical radiation has allowed people to stay on this earth with their loved ones much longer. However, as we have learned terrible, tragic, heartbreaking events can occur and have occurred when something goes awry with medical radiation therapy primarily in cancer patients.

I was greatly saddened to read the stories in the New York Times which included a tragic story about a breast cancer patient from my district who suffered a radiation overdose in 2006 when a physicist entered incorrect information into the treatment planning computer. Her name was Myra Jean Garman and she was in so much pain from the radiation overdose and resulting side-effects that she eventually committed suicide. According to the Ohio Department of Health there have been 18 incidence reports with respect to medical radiation over the past 2 years. Obviously, we want to reach a place where there is no need to file any incidence reports because there are no incidents.

Patient safety must always be our primary concern and patient safety in radiation therapy as well as patient safety in diagnostic radiation, are critical. We are here today to learn about the best way to ensure patients are protected to ensure that patients are given the right tests at the right time and that no patient ever suffers through a radiation overdose, to ensure that our medical equipment is safe and that our workers are well-trained, and I look forward to learning about the issues surrounding medical radiation from our witnesses today and I thank the witnesses for being here to deal with this very complex issue.

And I yield back my time.

Mr. PALLONE. Thank you.

We are going to have votes and I know there are quite a few and I think they are the last ones of the day. I will find out soon but just so that we probably are not going to get the panel before the votes. We will try to do as many openings as we can and then you will have to wait around probably an hour or so for us to come back, unfortunately.

Next is the gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I want to thank the Parks family for their attendance and being here. We know it is not easy.

I want to concur with the comments of the Chairman. Radiation therapy has been very successful in saving lives. Early diagnosis and early treatment has prolonged the lives of thousands of Americans and this should be in no way an attempt, not an attempt but

we don't want to scare people away from doing this and some of these stories are starting to do that and we just have to be careful. You know, cancer survival rates have gone from 50 percent to upwards of 95 percent in many cancer cases and that is because of this technology in this. We have to address, identify the problem, encourage people to move forward so these mistakes don't occur and in this case it would be software applications and training. In talking with health care professionals and the like, a scalpel in the hands of a trained professional does great good. A scalpel in the hands of someone who is untrained does great harm and that is, I hope, the focus of this hearing and we look forward to the testimony. We do thank the Parks family and those who have suffered loss and your testimony is very, very important because it helps us focus on the truth.

And I yield back, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Shimkus.

The gentleman from Georgia, Mr. Barrow, and sponsor of the bill that we mentioned before.

Mr. BARROW. Thank you, Mr. Chairman and thank you for holding this hearing to call attention to the serious problem of accidents and errors in the delivery of radiological services.

While we can't expect either the people or the technology to be perfect, when you go into a doctor's office or you enter the hospital you have the right to expect a certain level of competence and training from the people taking care of you. I am the lead sponsor of the Care Bill which will set minimum educational and certification requirements for the technical personnel who perform medical imaging and radiologic therapy. Most people are surprised to find that many States don't license or regulate radiologic technologists at all. Common sense tells us that properly educated and certified personnel will produce better medical outcomes, not only that but more efficient delivery and reduction in duplicative testing and waste will also cut costs. I recognize that the problems highlighted by recent media reports are likely to require multifaceted solutions but I am convinced that we must start by ensuring that the workforce is properly trained and certified.

With that, I yield back. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Barrow.

The other gentleman from Georgia, Mr. Gingrey.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. GINGREY. Mr. Chairman, thank you.

Whether used in the detection or treatment of patients, medical radiation has become an important part of medical care in this country. From the latter half of the 20th century through today we have seen this technology evolve and add to the quality of health care in our country. As an OB/GYN physician for nearly 30 years, I have seen firsthand the benefits of this technology for the health and welfare of my patients. The chances of survival for a cancer patient, as already mentioned, are increased exponentially the earlier cancer is detected.

During this Congress we have heard from patients and indeed members of Congress alike who credit their health and their wel-

fare to the early detection of cancer. For others radiation treatments like chemotherapy prove the decisive factor in life or death. Ms. Lindley is one such patient who credits Selective Internal Radiation Therapy with saving her life and thank you for coming before this committee and sharing your story with us today, Ms. Lindley.

Unfortunately for all of the benefit that patients see from such technology, there are also troubling stories of trauma and sorrow. The story of James Parks is one such case and the trauma his son, indeed his whole family endured because of a radiation accident is a sobering tale. His story reminds us how important adherence to proper safety protocols is as well as the review of adverse medical events can be to the overall health of all of our patients.

Earlier this month the Food and Drug Administration announced a new initiative to reduce unnecessary radiation exposure from medical imaging. Therefore, this is a very timely hearing and I would like to thank Chairman Pallone for calling it today, however, I would like to sound one note of caution. Remember the furor that surrounded the United States Preventative Services Task Force recommendations on mammography screenings that had this information, of course, has not faded from the psyche of this country. That incident and the Congressional hearings that followed outline for this committee the importance of protecting the rights of patients and their physicians to decide what medical treatments are appropriate. Medicine is an art form. It can be taught from a book but it must be practiced with medical experience and yes, balanced judgment.

With that thought in mind I want to thank all of you witnesses for coming before the committee today. I look forward to hearing from you and the question period.

I yield back, Mr. Chairman, my time.

Mr. PALLONE. Thank you.

I am going to try to get two more members in so I guess that would be Ms. Eshoo and Mr. Green, and then we are going to have to break but we will continue after if anyone, you know, for those who come back.

The gentlewoman from California.

Ms. ESHOO. Thank you, Mr. Chairman, for holding this important hearing.

I think all of us in reading the recent articles on vulnerable patients and what happened to them, we are really stunned by it. That is number one. Number two, I can really track over just the period of time that I have been a member of Congress. This is my 18th year and the co-chair of the medical device caucus, tremendous improvements in this area which holds out so much hope for especially cancer patients in our country. But clearly, something needs to be done in the area of supervision, the area of licensing and that we in my view need national standards in this area because it is right now it is catch-as-catch can so my, I will submit my full statement for the record.

I look forward to hearing from the witnesses. This is an important hearing. If we need more information, I will certainly participate in all of the hearings so that we come up with a framework

that really fits what the problems are so that no one is subjected to the over-radiation that we have read about.

I also would like to ask for a unanimous consent request that Mr. Waxman's statement for the record be accepted and that he has a—let's see, a statement for the record that is relative to a 52-year-old who is a constituent of his, you know, and the father of three children in Los Angeles and what happened to him relative to excessive radiation at Cedars Sinai Medical Center in Los Angeles.

[The statement of H. Michael Heuser follows:]

**Statement by H. Michael Heuser to the Committee on Energy & Commerce,
United States House of Representatives
February 26, 2010**

My name is H. Michael Heuser. I am a 52 year-old father of three and I live in Los Angeles, California. I am, according to the California Department of Public Health, "Patient 1", or the first patient discovered to have been subjected to excessive radiation overdosing while a patient at Cedars-Sinai Medical Center in Los Angeles.

My discovery in August of 2009 brought to light the radiation overdosing of 259 other patients by CT brain perfusion scans at Cedars-Sinai. As the Food & Drug Administration has confirmed to me, the discovery of my radiation overdosing at Cedars-Sinai triggered their nationwide alert regarding CT brain perfusion scans to hospitals across the country and ultimately "resulted in local, state and federal investigations."

I found out about my radiation overdosing after I went completely bald in a perfectly symmetrical 4-inch wide band that extended from ear to ear all the way around my head. I have provided a photograph to the Committee for reference.

I had three CT brain perfusion scans during a two-week hospitalization at Cedars-Sinai following a stroke on July 4, 2009. At the time, CT brain perfusion scans at that hospital were exposing patients to eight times the allowable radiation level. This excessive radiation overdosing had been going on undetected for 18 months at the hospital.

According to the Food & Drug Administration's Center for Devices and Radiological Health, one CT brain perfusion scan is the equivalent of several hundred chest x-rays. With 3 CT brain perfusion scans at eight times the usual radiation dose, plus several regular CT head and neck scans, it is safe to say that I was exposed to the equivalent of roughly 10,000 chest x-rays to my head. Using recent research reports from the University of California San Francisco, I calculate that I was exposed to roughly 12 times the level of radiation exposure that caused increased cancer risk to people near atomic bomb blasts.

Aside from being shocking and outrageous, this radiation overdosing never had to happen and never should have been allowed to happen. The system is clearly broken when patients trust that certain medical devices will help or save them only to be harshly betrayed with consequences that could have been avoided altogether had someone been paying attention.

As the patient responsible for helping expose this serious public health issue, I am pleased that the U.S. House of Representatives Committee on Energy & Commerce Subcommittee on Health is holding hearings on this critical matter. As a person who will have to live with a constant fear of developing cancers and other maladies from my excessive radiation exposure, I hope Congress will push for meaningful changes now so that others are not exposed to such extreme levels of radiation by medical devices in the future.

We must change the current system that allows medical devices, which can produce dangerous and sometimes deadly levels of radiation, to reach the market with little oversight and regulation.

I urge Members of the Committee to pay particular attention to the lack of built-in safety protocols for these medical devices manufactured by General Electric and others.

I also urge Members to look closely at GE's involvement in the 18 months during which the radiation emitted by the GE scanners was devastatingly high at Cedars-Sinai. It is my understanding that GE technicians help service and provide oversight for the devices they manufacture, market and sell to hospitals. This clearly did not happen at Cedars-Sinai.

I am prepared to testify before the Committee at any point in time. I also hope the Committee will bring GE Healthcare executives and other medical device manufacturers before Congress to testify on this critical public health issue to account for their role in the crisis and to acknowledge what they knew about excessive radiation caused by their machines and when they knew it.

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Mr. PALLONE. Without objection, so ordered.

Ms. ESHOO. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

I think we can get two more in on this so and Ms. Christensen wants to stay. We will start with Mr. Green and then go to Ms. Christensen.

Mr. GREEN. Thank you, Mr. Chairman.

I ask unanimous consent my full statement be placed in the record.

[The information was unavailable at the time of printing.]

Mr. PALLONE. Without objection, so ordered.

Mr. GREEN. First, I am glad you are having this hearing. A lot of us read the information and our health subcommittee has worked for many years on expanding opportunity for CT scans and treatment because of the new technologies are changing everyday and I will give my own example. I went about 7 years ago in Houston Heart Institute and they had a concern about a problem and I did a scan of my heart, an image of my cardiovascular system and that was great. I went back a few years later but staff and the equipment had already changed because we are seeing better equipment every day and we don't want to lose that ability to diagnose and to treat in the case of cancers. The problem is that if we don't deal with this, we will scare both practitioners and also patients away from it.

So that is why the hearing is so important today, Mr. Chairman. Thank you for doing it. We need to get it right because the next generation of treatment can be less invasive than what it is now but we surely don't want to stop it because people are scared they are going to be over-radiated, a person is not trained to use the equipment they are using or that it is not the proper dosage.

So, Mr. Chairman, thank you and I look forward to working with you and see what we need to do to deal with it.

Mr. PALLONE. Thank you.

The gentlewoman from the Virgin Islands.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and thank you for holding this hearing.

I would also like to ask that my full statement be included in the record.

You know, as a physician the practice for if I include my residency maybe 25 years, I have had the opportunity to see the benefits that the diagnostic and therapeutic radiology have and I am sure everyone of us on this committee either ourselves or in our family have seen those benefits firsthand. But we always have to balance the benefits and the risks and in favor of the benefit to the patient and minimizing the risk. So we have seen some instances recently where—and this has happened over the years—where people have been over-radiated and have had severe repercussions because of it and we have at least one vehicle before us that can rectify this and it is something that we must do.

And I look forward to working with my colleagues to ensure that when individuals go for either diagnostic reasons or therapeutic reasons that they are not harmed by the machinery and the radiation. And so I look forward to hearing the testimony of our wit-

nesses this morning and your comments on how we can improve the safety of radiation for our patients. Thank you.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

I think we have at least an hour of votes so we will come back after that. If anyone else comes back, we will let them do an opening statement, otherwise we will go right to you but we were talking I am sure no earlier than 11:30. Thank you.

The committee is in recess.

[Recess.]

Mr. PALLONE. The subcommittee hearing is reconvened and we still have some opening statements starting on our side with our Chairman, Mr. Waxman, from California.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Chairman Pallone, for holding this important hearing and I know we are anxious to hear from our witnesses and I regret that we had the votes that interrupted our hearing.

But we are looking today at the extraordinary benefits and examining the possible risks associated with the use of radiation in medicine. And let me be clear at the outset, diagnostic technologies like CAT scans that identify tumors and therapeutic procedures such as radioactive seeds that treat prostate cancer are potentially lifesaving. They are important interventions in our medical toolbox and our health care system is unquestionably much better because of them.

But recent reports and studies have raised questions about the relative safety of these technologies. No medical intervention is 100 percent safe and patients' individual tolerance for risks and being exposed to such procedures varies as well. These are dangers that generally cannot be avoided altogether but the purpose of this hearing is to learn more about those risks and hazards from radiation that would appear to be preventable and there have been recent examples as reported in the press. Investigators at the NRC found that a cancer unit at the VA hospital in Philadelphia botched 92 out of 116 procedures using radioactive seeds to treat patients with prostate cancers. Over 200 patients were mistakenly exposed to up to eight times the normal dose of radiation during brain scans at Cedar Sinai Hospital in Los Angeles. Because of a computer error that went undetected, Scott Jerome-Parks, the son of one of today's witnesses was blasted with excess radiation on three consecutive days during his treatment for tongue cancer. Scott died from his radiation exposure at the age of 43. Despite these patients' need and consent for the lifesaving technology used, the end result clearly is not what they signed up for.

Alarmingly, as we will hear from a number of today's witnesses, these are not isolated cases. The mistakes made in these instances while perhaps not widespread, we hope not widespread, appear to be more than just random and rare. They are occurring all across the country and in hospitals and physician offices alike.

The reasons for this poor quality of care would seem to be multifaceted. Whether it is a lack of standardization of equipment or laxity or even nonexistent State licensing requirements for machine operators or outdated Federal oversight authority, experts tell us that more can and should be done to reduce unnecessary radiation exposure and medical errors. Indeed, action has already been called for by the medical imaging manufacturers and some radiation provider groups whom we will hear from today.

As we move forward I would hope that we can all agree on two basic premises. First is the enormous medical value of our various radiologic techniques. As I mentioned earlier we want to underscore the point again both diagnostic and therapeutic radiology interventions save lives and we want them. We need them. Second is the obligation to ensure that these interventions are as safe as they can be and that everything is being done to make that a reality. Patients are entitled to nothing less. With these principles in mind, I believe our job today is simple and straightforward—to understand how to lower the risk associated with radiation in medicine to make it as safe as possible without reducing its many benefits to patients and researchers.

We have an outstanding group of witnesses. It is no longer this morning. It is afternoon. They are here to help us learn more about these issues. I thank each of them in advance for their testimony and I look forward to hearing from them but in my case from reading their testimony because I am compelled to go to a meeting with the Speaker on health care which will require me to miss the testimony but I will have a chance to review and I thank the witnesses for being here.

[The prepared statement of Mr. Waxman follows:]

**Opening Statement of Chairman Henry A. Waxman
Committee on Energy and Commerce
Subcommittee on Health
Hearing on “Medical Radiation: An Overview of the
Issues”
February 26, 2009**

Thank you, Chairman Pallone for holding this important hearing.

Today we will look at the extraordinary benefits and examine the possible risks associated with the use of radiation in medicine. Let me be clear at the outset: Diagnostic technologies like CT scans that identify tumors and therapeutic procedures such as radioactive seeds to treat prostate cancer are potentially lifesaving. They are important interventions in our medical toolbox and our health care system is unquestionably much better for them.

But recent reports and studies have raised questions about the relative safety of these technologies. Of course, no medical intervention is 100 percent safe. And patients' tolerance for risk in being exposed to such procedures varies as well – a person is more likely to accept a potentially fatal side effect for a therapy to treat a lethal cancer than for a less serious disease. These are dangers that generally cannot be avoided altogether.

The purpose of today's hearing is to learn more about those risks and hazards from radiation that would appear to be preventable. Some recent examples as reported in the New York Times:

- Investigators at the Nuclear Regulatory Commission found that a cancer unit at the VA hospital in Philadelphia botched 92 out of 116 procedures using radioactive seeds to treat patients with prostate cancer.

- Over 200 patients were mistakenly exposed to up to eight times the normal dose of radiation during brain scans at Cedars Sinai Hospital in Los Angeles.

- Because of a computer error that went undetected, Scott Jerome Parks -- the son of one of today's witnesses -- was blasted with excess radiation on three consecutive days during his treatment for tongue cancer. Scott died from his radiation exposure at the age of 43.

Despite these patients' need -- and consent -- for the life saving technology used, the end result clearly is not what they signed up for.

Alarmingly, as we will hear from a number of today's witnesses, these are not isolated cases. The mistakes made in these instances, while perhaps not widespread, appear to be more than just random and rare – they are occurring all across the country and in hospitals and physician offices alike.

The reasons for this poor quality of care would seem to be multifaceted. Whether it is a lack of standardization of equipment, or lax and even non-existing state licensing requirements for machine operators, or outdated federal oversight authority – experts tell us that more can and should be done to reduce unnecessary radiation exposure and medical errors. Indeed, action has already been called for by the medical imaging manufacturers and some radiation provider groups whom we will hear from today.

As we move forward, I would hope that we can all agree on at least two basic premises. First is the enormous medical value of our various radiologic technologies. I mentioned this earlier, but want to underscore the point again: Both diagnostic and therapeutic radiology interventions save lives. We want them. We need them.

Second is the obligation to ensure that these interventions are as safe as they can be – and that everything is being done to make that a reality. Patients are entitled to nothing less.

With these principles in mind, I believe our job today is simple and straight forward – to understand how to lower the risks associated with radiation in medicine to make it as safe as possible without reducing its many benefits to patients and researchers.

We have an outstanding group of witnesses this morning who are here to help us learn more about these issues. I thank each of them in advance for their testimony and look forward to hearing from them.

Mr. PALLONE. Thank you, Chairman Waxman.

The gentlewoman from North Carolina, Mrs. Myrick.

Mrs. MYRICK. Thank you, Mr. Chairman, and for the sake of time I am going to submit my statement for the record along with a letter from the Society for Radiation Oncology Administrators.

[The prepared statement of Mrs. Myrick follows:]

Medical Radiation: An Overview of the Issues

February 26, 2010

Rep. Sue Myrick, Opening Statement

- Thank you, Mr. Chairman. Welcome, to our many witnesses.
- I realize that this hearing touches on both radiation therapy and medical imaging in general, but I'll focus my comments on radiation therapy.
- I'm a beneficiary of radiation therapy. We know for a fact that this treatment, done properly, kills cancerous tumors and extends life.
- [Insert a few details about your experience with radiation therapy]
- It's also tragically apparent that this delicate and potent treatment can, in a **tiny** fraction of cases, cause damage and even death for some patients.
- This should be addressed in a measured and responsible way.

- Radiation therapy involves complicated medical technology that requires training and expertise.
- There is bound to be a margin of error. But there must be a way to at least ensure that mistakes don't result in irreparable harm, and certainly not death-- death by attempted treatment, in this case.
- I hope that we can work together to address these risks in a sensible way.
- If the Chairman permits, I would like to submit a letter for the Committee record, from the Society for Radiation Oncology Administrators.
- This letter discusses current state regulation on mandatory reporting of medical errors, radiation therapy department policies that work to prevent these mistakes, and efforts to set a national minimum education standard for those who administer radiation through imaging or therapy.
- Thank you, Mr. Chairman, I yield back.

Mr. PALLONE. Without objection, so ordered.

Mrs. MYRICK. Thank you.

Mr. PALLONE. Thank you.

And so I think we have had opening statements from everyone else so we will move to our panel and let me introduce each of the panelists if I could. Beginning on my left is Mr. James and Mrs. Donna Parks from Gulfport, Mississippi. Thank you for being with us today and Suzanne Lindley from Canton, Texas. And then we have Dr. Rebecca Smith-Bindman, who is Professor in Residence, Radiology and Epidemiology and Biostatistics, Obstetrics, Gynecology, and Reproductive Medicine. I didn't realize you have all those at the University of California in San Francisco. And then we have Dr. Eric Klein who is Professor of Radiation Oncology at Washington University in St. Louis. And then we have Dr. Cynthia H. McCollough who is Director of the CT Clinical Innovation Center, Department of Radiology at the Mayo Clinic and Professor of Radiological Physics at the College of Medicine at the Mayo Clinic. That is our panel. We ask you to give us 5-minute opening statements if you can limit it to that please and your statements, your full statements become part of the record. Then we will have questions from the panel. I should mention that beyond this you may get additional written questions from the panel within the next 10 days or so, as well.

We will start with you, Mr. Parks. Thank you for being here. Let's make sure that your microphone is on. It should be the green light and maybe bring that a little closer to you, Mr. Parks, so that we can.

STATEMENTS OF JAMES AND DONNA PARKS, GULFPORT, MISSISSIPPI; SUZANNE LINDLEY, CANTON, TEXAS; REBECCA SMITH-BINDMAN, M.D., PROFESSOR IN RESIDENCE, RADIOLOGY AND EPIDEMIOLOGY AND BIostatISTICS, OBSTETRICS, GYNECOLOGY, AND REPRODUCTIVE MEDICINE, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO; ERIC E. KLEIN, PH.D., PROFESSOR OF RADIATION ONCOLOGY, WASHINGTON UNIVERSITY IN ST. LOUIS; AND CYNTHIA H. MCCOLLOUGH, PH.D., DIRECTOR, CT CLINICAL INNOVATION CENTER, DEPARTMENT OF RADIOLOGY, MAYO CLINIC, PROFESSOR OF RADIOLOGICAL PHYSICS, COLLEGE OF MEDICINE, MAYO CLINIC

STATEMENT OF JAMES PARKS

Mr. PARKS. Mr. Chairman and committee members, we want to thank you for the opportunity of coming here to talk.

We are here to testify on behalf of our son, Scott, who died from an extreme overdose of radiation by a very inept team of therapists using a linear accelerator. It is a horrible way to die. What was to be a minimally invasive procedure turned out to be a 2-year nightmare for the whole family, especially he and his wife. They were in New York City and that is where most of this occurred. We were with Scott and Carmen when Scott's feeding tube was implanted. At that time we had been convinced that we were doing the right thing. He had not wanted a surgical procedure which would have been very bad. My hearing aid just went out.

So he chose what he called the laser treatment and we thought it would be very quick. After the implant we thought that was just sort of an inconvenience that would be temporary but it didn't work out that way.

We in Mississippi and our son was in New York so what you get here are snapshots in time as to when we saw him. His wife, Carmen, of course, was with him every moment of every day for 2 years and suffered all of the things he suffered but she can't speak because of a gag order and it is tied to her financial settlement. She is the one who should be here and isn't. She knows everything that has happened.

Each time we would go visit, about every 3 or 4 months we would see him and of course he would change dramatically every time we would go. I am not sure all patients do this but he rapidly became blind and deaf and he had constant pain and vomiting. He became extremely weak and sleepy. We couldn't hardly—he could last for about 15 minutes but he always kept his interests in Carmen. He said he would keep himself alive to make sure that she was all right and he did that. We admired him for suffering so much until the process ran its course and that she was finally taken care of.

We met him for the last time at Christmas when he called us all together, his brothers and aunts and Donna and I, and we had Christmas with him, and it was very, very touching. One of his friends had sent a big box and in the box was sand and two pails, and on the video that he made he said just lay back and put your feet in the sand and pretend that you are back in Mississippi where you should be, and Scott did that and he wasn't hardly with it at that time. This was at Christmas.

One of his problems was hiccupping. I don't know if that is he would hiccup all the time as you were talking to him, violent hiccups and of course his jaw was calcifying and his teeth were falling out. He couldn't eat. He didn't eat anything from the time he got the stomach implant until he died and he used to like to eat but all he would go to Central Park and this is he would sit on a bench and feed himself with the liquid meals that he would have and that was remarkable for him to do that.

The way it unfolded, he had four successful treatments. On the fifth one it was a terrible onslaught to him. His head swelled up and he suddenly became retching. His wife was there and she got alarmed and asked them to stop the treatment but they ignored her and this went on for a second time and then a third time when the machine was wide open and he got blasted with unguarded amounts of radiation. The hospital I think made an error in that they told Scott that this has never, ever happened before and that there was be something wrong with him because the machine always works perfectly. Of course, they found out that wasn't true and as for when Scott went into this he knew he was going die. He and his doctor were very close. They were and he went on kind of a mission to make his dying a cause for him to live for as long as he could and he stayed all through all the suffering and until finally there was a financial settlement. And he told me that Carmen was the reason he was staying alive and at the Christmas party I remember hugging him and he whispered to me very weak-

ly that Carmen is going to be all right and he can die now. He says I am ready to go and he, after we left at Christmas, he was very rapidly got much worse and soon died.

It was traumatic for all of us, particularly his wife, Carmen, and she was wanting to testify and, of course, she can't do that and it is a shame that this is a secret that we aren't supposed to talk about and that is why we are here. I told him I would do what I could and what I did is wrote a staving obituary for him which didn't do any good and I wrote a letter to the editor which didn't do any good. And by some miracle, I don't know how it happened but the New York Times picked up on this whole issue and has gone and it has snowballed. I think it is making an impact and that is exactly what Scott wanted. I am sure he is up looking down and he is very pleased.

I would like to say that we are not impressed with the machines. They are not as good as they could be and they must be improved to where they are—we have made a couple of recommendations and I would like to quickly read them. We must develop a strong mandatory database that we don't have and all medical institutions should report to the database and it could become a repository for evaluating trends and identifying medical problems, all medical problems not just radiation. The Veterans Administration has developed a reporting system that reports and responds to medical accidents called NCPS. That is all I know about it but it works in the VA system very well and I think it would be nice if the whole country would adopt such a thing. We are very encouraged that the SBA has taken a regulatory role in radiology and I understand the IMRT systems will be involved in that, too.

We ask the medical equipment manufacturers to develop a failsafe interactive expert system that can interact with human technicians to reduce and eliminate human errors. I think that is what really killed Scott was human errors and the machines must talk to the technicians and, of course, the technicians should be very trained. Oncologists and supervising physicists must learn to micromanage their radiology departments. That is the only way they will work. If you don't do that you are going to have people dying. It is outrageous to us that untrained and unskilled workers can get anywhere near this dangerous equipment but they do and it happened in Scott's case.

Thank you.

[The prepared statement of Mr. Parks follows:]

Mister Chairman, and members of the subcommittee, thank you for the opportunity to present this statement on this important issue.

We are to here testify at this hearing to make public our son's terrible ordeal and death due to a radiation accident. When our son learned that the over-exposure to radiation was to take his life, he felt he had a mission to prevent this atrocity from happening to others. He asked that all of us work to make his suffering and death have some meaning. He confided to us that he was worried about his wife, and must stay alive until he knows she will be OK. After more than two years of hideous agony he let himself die hoping that his ordeal might save many others from the same terrible suffering. Scott's primary care giver, his wife Carmen, suffered through every moment of every day for over two years as she helplessly saw her husband go blind, and deaf, and lose his teeth with his face contorted with gangrene tissue over his ear and scalp.. He suffered constant, acute pain and vomiting every day with constant hiccupping that he had to cope with as best he could. Perhaps unfortunately, his brain was least affected during all but the last stages, and he was aware of all that was happening to his body. The last time we saw Scott, at our Christmas family gathering for him, he was a caricature of what our son used to be. He became a helpless invalid at the end. He did whisper to me that "Carmen will be OK. I'm ready to go." What we can give you are only snap shots in time since we could visit Scott only every 3 or 4 months. The person who knows every detail of the tragedy is Carmen, but she must remain silent because of a gag order tied to the financial settlement. It is the hospital's way of making serious accidents a guarded secret. Our son's widow should be here testifying to this panel, but she must remain silent.

My wife and I have devoted our entire professional careers to working in hospitals,. Donna as a registered nurse and I a psychiatric social worker. After all of our years of service, we are particularly appalled that a hospital killed our son. We know how hospitals work. We know that medical accidents happen. We know that hospitals have a vested interest in making serious accident go away as quickly and quietly as possible. Hospitals in general cannot be relied upon to report or make public, serious medical accidents without strong external sanctions.

From our point of view, we have two recommendations to be considered.

1. The United States must develop a strong, mandatory, data base, and force all medical institutions to report all serious medical accidents. It would be a repository for evaluating trends and identifying medical problems throughout the nation. In order to work it must have the ability to force compliance on threat of fines and imprisonment. The Veterans Administration has developed a model system of reporting and responding to medical accidents called NCPS that is working well within the 158 V.A. hospitals. A system like that should be developed for all medical facilities. At present only few states have any semblance of reporting capability and there is almost no coordination among states. We are pleased to learn that the FDA is taking a regulatory role in Radiology that will include IMRT operations.

Mister Chairman, and members of the subcommittee, thank you for the opportunity to present this statement on this important issue.

2. We ask that medical equipment manufactures of deadly machines develop failsafe interactive expert systems that can interact with human technicians to reduce, or eliminate human errors. It is further recommended that such dangerous equipment never be operated by anyone not fully trained and qualified. Oncologists and supervising physicists must learn to micromanage every aspect of the Radiology Department. It is outrageous that any untrained and unskilled personnel can get anywhere near such dangerous equipment.

Mr. PALLONE. Thank you very much, Mr. Parks and also Mrs. Parks, for being here. I mean I know how tough—I shouldn't say I know. It had to be tough for you to be here and give us your testimony but it is really important because this is the very thing that we are trying to prevent in the future so I don't know what to say but to say that it at least your being here in some way, you know, can maybe make up in some way for your loss and at least you are trying to prevent it from happening to others. Thank you.

Mr. PARKS. Thank you.

Mr. PALLONE. Ms. Lindley. Ms. Lindley, I think you got to turn that on and move it closer to you. Otherwise we can't hear you. I think it is still not on. Is the green light on? I don't think it is on. I hate to bother you but is the green light on? Do you want to try Mrs. Parks' there maybe.

STATEMENT OF SUZANNE LINDLEY

Ms. LINDLEY. As a patient, I too want to make sure that I am in safe, qualified hands when I have treatment and it is hard to follow a story like yours, especially when mine has been the complete opposite. Thank you for having me today and as a resident of Canton, Texas I would also like to say a special hello to my fellow Texans on the committee, Congressman Green, Gonzalez, Hall, Barton and Burgess. I am honored to be here to share my experience as not only a cancer survivor but as a patient advocate.

I am here because of cancer research, because of medical imaging technology and because of radiation therapy. I was 31 years old when I was diagnosed with cancer. That was 11 years ago. It was then that I was diagnosed with stage four colon cancer and there are only four stages. Mine was the very most advanced. We found out that I had tumors that had already spread to my liver and I was told that I had about 6 months to live. We were scared. We were sad and we planned our first Thanksgiving as though it would be my last vacation or holiday with family. My daughters were 8 and 11 years old. We focused on the fact that I was going to die and we very much lost sight of the fact that I would live.

I posted a note on an online server asking for guidance from other cancer patients on how to prepare my two young daughters for life without me and instead of answering my question, a gentleman wrote back, Shelly Whiler, and said that he too was going through stage four colon cancer and I should look for some hope and that is what we did. I started with the only chemotherapy that was available, 5-FU. It had been around for 30 years. I was fortunate that colon cancer research was rampant and as my cancer progressed I was able to benefit from each new treatment as it was developed. That worked about 6 years and then the cancer began to spread. There were no more approved options so we went into clinical trials and those bought me a little bit of time, too. Then my liver became just laced with tumors. They were multiplying to the point where it looked like the stars lit up the sky at night. My stomach was swollen. My skin was yellow and I was tired. Every breath, every move was hard and the doctors said that there was nothing else that they could do and that basically I should call in hospice and that my condition was terminal.

We prepared my family again and I sent out an e-mail to friends letting them know that I was at the end of the line. Then after calling hospice, planning a funeral and picking out a casket, I got a phone call from one of the friends that I had written a letter to and he told me about his doctor in Wisconsin that was using Selective Internal Radiation Therapy. And they are little radioactive beads that are implanted internally and they attack the liver tumors and they leave the healthy tissue healthy. It sounded too good to be true and so at first I was hesitant to call the doctor. And then he kept calling me a dozen times that day and finally I picked up the phone and I called the doctor and we talked for awhile and it turned out that I was a good candidate for the treatment. I went back to my oncologist and I told him about the procedure and thought he would be really, really excited for me and instead he said, you know, I don't think it is going to help you, and then he turned around and said what do you have to lose. No one knew how much I had to gain.

I received the outpatient treatment called radio embolization in January of 2005, and I call them little, magic beads. After a 6-month period we saw a 65 percent of shrinkage and then after awhile we started seeing necrosis of those tumors so they were literally dying from the inside out. My belly started to get back to where there wasn't fluid in it. My color came back and I began to live again. I learned how to scuba dive. I went skydiving. I started telling my private story in very public places. I connected with other people and I met and shared experiences that I had never seen if it hadn't been for this disease or these treatments. I have continued with systemic therapy and I have also received additional targeted radiation treatments to stay ahead of the curve. I have had external beam radiation for tumors that spread to my spine and that has helped me with the pain control and has given me a better quality of life. I have had Gamma Knife used to treat a brain lesion. I have had radio frequency ablation to treat a returning liver tumor and I have had Cyberknife for lung tumors and they have all given me a little bit more time with my kids.

When you start anything new and especially a new treatment, you hope for the extreme. You pray for the best. You prepare for the worst and you don't really know what is going to happen but all you have is hope. These advance radiation therapy technologies have given me that hope. They have allowed me to watch my daughters grow up, to see them walk across a stage for graduation, to start college and to become adults. They are 19 and 22 now and are both in college. These treatments have allowed me to walk hand-in-hand with my husband and hopefully we will have more of these treatments and we will be able to spend our rocking chair days together.

I still have tumors here, there and everywhere. Systemic therapy after 11 years is just now part of my normal routine. Along with that, I will continue to use the targeted radiological therapies when needed. They allow me to live with colon cancer as a chronic condition and not a terminal one. These existing treatments and medical innovations will be a part of my life until there is a cure for this disease. What they have been able to give me is nothing short of miraculous. The grandest miracle is the realization that I am not

dying from cancer. I am living fully in spite of it. I have reaped the benefits of research, of dedicated tumor doctors and increasing options. In my arsenal there has been 5-FU Fluorouracil, with Leuovorin, Irinotecan, Oxaliplatin, free clinical trials, numerous surgeries, radio frequency ablation, Gamma Knife and vertebroplasty. None of these, other than the 5-FU existed when I was diagnosed. It is important that the momentum continue and that it is not thwarted, not only for me and for my family but for the 1,500 Americans that will lose their lives today and each and every day after today.

Before I close I want to leave you with this one thought. As my personal story makes painfully clear there are barriers out there already and I realize that you are not trying to build those barriers and that you are trying to make them safe but we also don't want to scare patients or take away their hope at the same time. Thank you.

[The prepared statement of Ms. Lindley follows:]

**House of Representatives Committee on Energy and Commerce: Subcommittee on Health
Medical Radiation Hearing: February 26, 2010
Suzanne Lindley Testimony**

Mr. Chairman and Ranking Member, thank you very much for your invitation to testify at this hearing today on medical radiation. As a current resident of Canton, Texas, I'd also like to say a special hello to my fellow Texans on the Committee: Congressmen Green, Gonzalez, Hall and Burgess. I am honored to be here to share my experience as a cancer survivor and patient advocate.

To put it simply – I would not be here today without medical imaging technology and advances in radiation therapy.

My battle with cancer began in 1998, when I was only 31 years old. It was then that I was diagnosed with stage IV colon cancer – the most advanced stage of the disease. I found out that the cancer had already spread to my liver and I was told that I had just six months to live.

For a short time, I thought that was it. My husband and I were planning Thanksgiving as if it would be my last holiday with our family and I posted a note to the Association of Cancer Online Resources (ACOR) list-serv, asking for guidance from other cancer patients on how to tell my two young daughters that I would not be around for much longer. Sadly, in many ways, I was overlooking the fact that I was still very much alive.

Rather than answering my question, I was fortunate that one of the patients who responded to my post – Shelly Weiler – urged me to get a second opinion instead.

With little time left, I did just that and started receiving what was the only therapy for colon cancer available at that time – chemotherapy (5fu). I cycled through many different types of chemo, often seeing short term results, only to then see the cancer grow stronger. When I was out of approved chemotherapy options, I turned to clinical trials.

My liver tumors began to grow and multiply. They were innumerable. . . . like the stars lighting the sky at night. My stomach was swollen, my skin was yellowing, and I was exhausted. Every breath, every move was difficult. After my all-too-brief reprieve of hope, I suddenly found myself back at square one. I was told that there were no more options and that I should come accept that my condition was terminal.

This time the prognosis was even more dire -- the doctors predicted that I had about three months to live.

We once again prepared family and I sent out an email to all of my friends letting them know that I had reached the end of the line. Then, after planning my funeral, picking out my casket and calling hospice, I received a call from one of those friends. "There is a new treatment that can save your life," he told me, urging me to call his oncologist in Wisconsin who had been using Selective Internal Radiation Therapy – tiny little radioactive beads that are implanted in tumors to reduce and eliminate cancer.

It sounded good. It sounded too good. With only three months, I was hesitant -- to say the least. I was afraid to get my hopes up again. My friend was persistent. He called dozens of times, and finally I relented. It turns out that I was a good candidate for the procedure.

I went back to my oncologist and told him about Selective Internal Radiation Therapy, expecting him to be excited. Instead he told me that he didn't think it would work – but then added “what do you have to lose?”

I received the outpatient treatment, called radioembolization (I call them little magic beads) in January, 2005 and over a six-month period saw a 65 percent reduction in my liver tumors as well as necrosis (or dying) of those tumors. More than that, the fluid in my belly started to disappear, my color returned, and my energy was back!!

I really began to live!

I learned to scuba dive. I have been sky diving. I have connected with other survivors, and have met people and shared experiences that I would have never seen had it not been for this very disease that will eventually end my life.

Since then, I have continued with systemic chemotherapy and I have also received additional targeted radiation treatments to stay ahead of the curve with my disease. I have received external beam radiation for spinal metastases (cancer that spread to my spine) – which has given me good pain control and enhanced my quality of life. I have also benefited from Gamma Knife, which treated a metastatic brain lesion, radio frequency ablation for a single returning liver tumor, and Cyberknife for my associated lung tumors (again keeping me one step ahead of the tumor growth).

Together, these advanced radiation therapy technologies have allowed me to watch my daughters grow up – to see them walk across the stage for their graduations, to start college, to become adults. Today they are 19 and 22. These technologies have also allowed me to walk hand in hand with my husband and will, hopefully, allow us to share our rocking chair days together.

I count myself blessed to be a cancer survivor during such a revolutionary time in the world of cancer treatments and to have been able to benefit from such amazing innovation. What these technologies are able to do, and what they have done for me, is nothing short of miraculous. They have turned miniscule moments into magical milestones.

Today, I still have tumors here, there, and everywhere. I continue to receive systemic chemotherapy and will continue to use targeted radiological therapies when needed. Cancer, for me, is chronic and not terminal thanks in a large part to procedures using medical radiation. These existing treatments, and ongoing cancer research and medical innovation, will be a part of my life until there is a cure for cancer.

Before I close, I'd like to leave you with this thought:

As my personal story makes painfully clear, there are enough barriers already out there, keeping patients from effective treatments: patients thinking, like I did, that they're at the end of the road, when in reality, there are not. The last thing we need is to add yet another barrier by invoking unwarranted fear about the radiation used in these miraculous procedures.

Thank you!

Mr. PALLONE. Thank you very much really for being with us today and sharing that. We appreciate it. Dr. Smith-Bindman. I guess the name is spelled wrong there. I am sorry. It says Binder.

Dr. SMITH-BINDMAN. That is how we spell it though.

Mr. PALLONE. All right, Bindman, thank you.

STATEMENT OF REBECCA SMITH-BINDMAN

Dr. SMITH-BINDMAN. Chairman Pallone, Ranking Member Whitfield and members of the Health Subcommittee, thank you for the opportunity to testify today.

My name is Dr. Rebecca Smith-Bindman, Professor of Radiology, Epidemiology and Biostatistics at the University of California, San Francisco School of Medicine. I am a clinical radiologist and my research focuses on assessing the risks and benefits of medical imaging.

My testimony today focuses on CT because it is one of the most common imaging tests we use and it is the test with the greatest potential for causing harm. CT uses x-rays to obtain extremely detailed images of internal organs and the development of CT is widely considered one of the most important advances in medicine allowing a more timely and accurate diagnosis of disease across every area of medicine. It is simply an extraordinary test and currently one in five individuals in the United States undergoes a CT scan every year.

Although CT scanning is useful, it delivers much higher doses of radiation than do conventional x-rays and exposure to radiation can lead to the development of cancer. To help put this into context, when you go to the dentist and you are offered dental x-rays some of you may pause to consider any potential harm from those x-rays. The most common type of CT scan that patients undergo in the U.S., an abdominal CT delivers approximately the same amount of radiation as getting 1,500 dental x-rays all at the same time. Additionally, newer applications of CTs such as those used to assess blood vessels in the brain require even higher doses of radiation, as much as 5,000 or more dental x-rays. The increase in the number of CTs and the higher dose for some CTs has resulted in a large increase in the population's exposure to radiation from medical imaging.

The National Council on Radiation Protection, a group dedicated to ensuring that the U.S. population is as safe as possible as it relates to radiation has estimated that the U.S. population's exposure to radiation from imaging has increased dramatically the risks. Exposure to radiation increases a person's risk of getting cancer. The National Academy of Sciences National Research Council reviewed all of the published literature on the health risks of radiation. They found people who received doses in the same range as a single CT would increase risk of developing cancer. Further, many patients in the U.S. receive multiple CT scans over time and their risks are even higher. Thus the doses that we experience everyday as part of routine CT scanning are potentially dangerous. The cancers may not develop for 5, 10 or 20 years. Even though we can't see the harms immediately, we must take them seriously.

Oversight for CT radiation dosing is very fragmented. The FDA oversees the approval of the CT scanners and medical devices but

does not regulate how the test is used in clinical practice. Radiologists determine how the CT tests are performed, however there are few national guidelines on how these studies should be conducted and therefore is great potential for practice variation that could introduce unnecessary harm for excessive radiation dosing. The American College of Radiology has established a voluntary accreditation process to try to standardize practice and collects dose information but only on a very small sample of tests. This approach is promising but at this point in time the data collection is extremely limited making it difficult if not impossible for the college to monitor facilities comply with their guidelines.

The manufacturers of CT equipment have begun work to establish standards of how radiation dose information should be measured and reported. However, the manufacturers have not adopted or implemented these standards.

My research team at UCSF conducted a study to assess the doses associated with typical CT scans. We collected radiation doses on over a thousand patients and found that for nearly every type of CT scan the radiation doses were much higher than commonly reported, that the doses varied substantially between different facilities and even within the same facility the doses varied dramatically between patients. As part of this study, we also quantified the risk of CT. We found that for some patients the risk of a single test could be as high as 1 in 100. That means of 100 patients who undergo a CT, one of them could get cancer from the test. This is an extremely high risk for a test that is supposed to find cancer, not cause it.

What needs to happen to improve the safety of CT imaging? Given the importance of CT and yes, its potential for causing cancer, it is imperative that we make CT scanning as safe as possible. To do this we need to do two things. First, we need to lower the dose from routine CT scans and second, we need to ensure that we use this technology only when necessary. To lower the dose several steps are important. We need very clear standards for what are acceptable levels of radiation exposure and there should be regulatory oversight for setting of these standards. Doses used in actual patients need to be monitored. Despite the potentially high radiation dose CT can deliver there is no regulation of CT practice in the United States. The dose information should be prominently displayed when CTs are done so that technologists can easily make adjustments if needed if the doses are too high. And lastly, the dose associated with each CT examination should be documented and recorded in each patient's medical record and this information should be tracked over time. Recording and tracking dose information would help educate patients and providers about radiation exposure and would lead to activities to minimize dose.

There are currently private businesses that offer full-body CT screening to healthy individuals. The FDA and most professional organizations have voiced concerns that using CT as a screening test could cause more cancers than they find. For diagnostic CT, these are tests that are done in patients who have a clinical problem who have a symptom. It is generally been thought that if the patient is sick enough to get a CT scan that the benefit of that test will outweigh any risk, however we have started to use CT scan-

ning so often and in patients who are really not very sick at all that we need to really think about whether the test is necessary and whether it could cause more harm than benefit. Neither physicians nor patients are aware of the risks associated with CT nor the importance of limiting exposures.

In summary, consensus is growing that efforts are needed to minimize radiation dose from CT and to ensure that patients receive the minimum dose necessary to produce a medical benefit. These efforts must include reducing unnecessary studies, reducing the dose per study and reducing the variation in dose across patients in facilities. Despite the frequency importance of CT imaging, there are no resources available to the research community to study or improve the quality of CT scanning. Creation of an academic consortium to study CT and make it as safe as possible would go a long way towards improving its utilization and safety.

Thank you for allowing me to contribute to this important discussion and I would be happy to answer any questions.

[The prepared statement of Dr. Smith-Bindman follows:]

Testimony of Rebecca Smith-Bindman, MD
Professor of Radiology, Epidemiology and Biostatistics,
Obstetrics, Gynecology and Reproductive Sciences,
University of California, San Francisco

Before

The Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

Medical Radiation: An Overview of the Issues

February 26, 2010

Chairman Pallone, Ranking Member Deal, and members of the Health Subcommittee, thank you for this opportunity to testify today. I am Dr. Rebecca Smith-Bindman, Professor of Radiology, Epidemiology and Biostatistics, at the University of California San Francisco School of Medicine. I am a clinical radiologist and I conduct research focused on assessing the risks and benefits of medical imaging. I recently published a paper in the Archives of Internal Medicine focused on safety of diagnostic CT and I have included a copy of this paper with my testimony.

My testimony today focuses on computed tomography – CT – because it is one of the most common imaging tests that we use in medical diagnosis, and the test with the greatest potential for causing harm.

CT uses x-rays to obtain extremely detailed images of internal organs, and the development of CT is widely considered among the most important advances in medicine. It is a simply an extraordinary test, allowing the more accurate diagnosis of disease across nearly every area of medicine. In part because it is so useful, the utilization of CT has risen dramatically and currently 1 in 5 individuals in the U.S. undergoes a CT every year.

Although CT is useful, it delivers much higher doses of radiation than do conventional x-rays, and exposure to radiation can lead to the development of cancer. To help put this into context, when you go to the dentist and you are offered dental x-rays, you may pause, in order to consider the potential harm associated with getting x-rays. The most common type of CT scan patients undergo in the U.S. – a CT of the abdomen – delivers approximately the same radiation as getting 1500 dental x-rays. Additionally, newer applications of CT, such as those used to assess the heart, or to assess the blood vessels in the brain, require even higher doses of radiation – as much as 5,000 or more dental x-rays.

The increase in the number of CT tests that are done each year, and the higher dose per CT test, has resulted in a very large increase in the population's exposure to radiation from medical imaging. The National Council on Radiation Protection, a group dedicated to ensuring that the US population is as safe as possible in relation to

radiation exposures, has estimated that the US population's exposure to radiation from medical imaging has increased 6 times since the 1980s.

Risks

Exposure to radiation increases a person's risk of getting cancer. The National Academy of Sciences' National Research Council reviewed all of the published literature related to health risks of radiation. They found people who received doses in the same range as a *single* CT scan were at increased risk of developing cancer. Further, some patients receive multiple CT scans over time – and their risks are even higher. Thus the doses that we experience every day as part of routine CT scanning are potentially dangerous. The cancers may not develop for 5, 10 or 20 years. Even though we can't see the harms immediately, we must take them seriously.

oversight

Oversight for CT radiation dosing is currently very fragmented. The FDA oversees the approval of the CT scanners, as medical devices, but does not regulate how the test is used in clinical practice. Radiologists determine how the CT tests are performed. However, there are few national guidelines on how these studies should be conducted and therefore there is great potential for practice variation that could introduce unnecessary harm from excessive radiation dosing. Furthermore, since information on radiation is reported differently across the different types of CT machines, it is difficult for radiologists to standardize their practice. The American College of Radiology has established a voluntary accreditation process to try to standardize practice, and collects dose information but only on a very small sample of tests. This approach is promising, but at this point in time the data collection is extremely limited, making it difficult if not impossible for the College to monitor if facilities comply with their recommendations. The manufacturers of CT equipment have begun work to establish standards of how radiation dose information should be measured

and reported. These steps could lead to collection, standardization and reporting of dose information that would improve the safety of CT. But, the manufacturers have not adopted or implemented these standards. As a result of this fragmentation, information on CT dose is extremely limited.

My research team at UCSF conducted a research study to assess the doses associated with typical CT scans. We collected radiation dose information on over 1000 patients and found that for nearly all types of CTs, the radiation doses were much higher than commonly reported, that the radiation dose varied substantially between different facilities, and that *even within the same facility*, that the doses varied dramatically between patients evaluated for the same clinical problem. For example, we found that one patient had 20-times the radiation dose as another patient for a routine head CT when both studies were done at the same institution.

As part of this study, we also quantified the risk of CT. We found that for some patients, the risk of a *single test* could be as high as 1/ 100. That means of 100 patients who undergo a CT, one of them could get cancer from that test. This is an extremely high risk for a test that is supposed to find cancer, not cause it.

There are private businesses that currently offer full body CT *screening* to healthy individuals. The FDA and professional organizations have voiced concerns that using CT as a screening test could cause more cancers than they find. For *diagnostic* CT- tests that are done in patients who have a clinical problem - it has generally been thought that if a patient is sick enough to get a CT scan, the benefit of the test outweighs any risk. However, we have started to use CT so often, and in patients who really are not very sick, that we need to think about whether the test is really necessary and whether it could cause more harm than benefit. Neither physicians nor patients are aware of the risks associated with CT, nor the importance of limiting exposures.

What Needs to Happen to Improve the Safety of CT Imaging

Given the importance of CT and yet its potential for causing cancer, it's imperative that we make CT scanning is as safe as possible. To do this, we need to do two things: first, we need to lower the radiation dose of routine CT scans; and second, we need to ensure we use CT only when necessary.

To lower the doses, several steps are important. We need very clear standards for what are acceptable levels of radiation exposure associated with CT and there should be regulatory oversight for setting of these standards. There is evidence that for many types of CTs the radiation dose can be reduced 50% or more without reducing quality.

Dose used in actual patients needs to be monitored. Despite the potentially high radiation doses CT can deliver, there is no regulation of CT practice in the United States, as the FDA does not have a legislative mandate to do so.

The default settings set by the manufacturers should be ones that yield the lowest possible doses and this dose information should be prominently displayed when CTs are done so that technologists can easily make adjustments as needed if the doses are too high.

And lastly, the dose associated with each CT examination should be documented and recorded in each patient's medical record and this information should be tracked over time. Recording and tracking this

information would help educate patients and providers about radiation exposure and would lead to activities to minimize dose.

Summary

In summary, consensus is growing that efforts are needed to minimize radiation exposure from CT, and to ensure patients receive the minimum dose necessary to produce a medical benefit. These efforts must include reducing unnecessary studies, reducing the dose per study, and reducing the variation in dose across patients and facilities. Despite the frequency and importance of CT imaging, there are no resources available to the research community to study or improve the quality of CT imaging. Creation of an academic consortium to study CT and to make it as safe as possible would go along way toward improving its utilization and safety.

Thank you for allowing me to contribute to this discussion and I would be happy to answer any questions.

Mr. PALLONE. Thank you, Doctor.
Dr. Klein.

STATEMENT OF ERIC E. KLEIN

Mr. KLEIN. Mr. Chairman and members of the committee, thank you very much for the invitation to come and speak here today.

My name is Eric Klein. I am a professor of radiation oncology at Washington University and have been a clinical medical physicist for 28 years. Over this time period, I have seen dramatic changes in terms of our profession's capability to diagnose and treat cancer. Our ability to image patients with modalities such as CT, MRI and PET allow us to visualize tumors and involved lymph nodes with millimeter accuracy. We can now customize how doses are delivered to tumors by performing sophisticated calculations allowing physicians to escalate dose to increase cure rates. Simultaneously we can reduce doses to critical organs, even those close to a tumor.

The delivery technique of intensely modulated radiotherapy, IMRT, which provides superior treatment delivery customization, comes with an increase in complexity in irradiation time compared with conventional radiation therapy thereby increasing risk. Thousands of hospitals and private treatment facilities all over the country have purchased IMRT machinery, often for competitive purposes and far too often without properly trained staff in place.

Hospitals need to ensure staffing levels are adequate not only in number but in expertise. There should be hands-on testing methods before therapists begin to treat patients with testing on a frequent basis. The training for all staff involved should include the consequence if something is incorrect. There can be as many as 100 steps in each process and each step must be understood by everyone involved especially those steps with greatest volatility. We do a good job teaching people what to do and what to watch out for but not the consequence or the impact if something is wrong. Though the anecdotal reported rate of errors in radiation oncology is quoted as less than one in ten thousand, there are two problems with this quoted rate. First, it may be inaccurate as there is no repository or statewide mandate for reporting such errors. In many States hospitals are not obligated to report errors occurring with a linear accelerator. A national repository for error reporting, anonymous or otherwise should be instituted in order for the community to learn from such errors or even near-misses.

The second problem with this low anecdotal reported rate is that it is still too high. Hospitals need to encourage scheduling patterns to allow for timeouts before each treatment begins to allow for cross-checking of all parameters by therapists. Related to this, the time leading up to a patient's first treatments should allow for careful review by the physicist of all parameters to be used. In addition, the manufacturers testing of radiotherapy delivery and treatment planning equipment should include fault testing and compatibility between systems.

In regards to medical physicists, we are the vital interface between physicians' orders and the eventual treatment. We are responsible for many things including the accuracy of the images used for the treatment plan, the validity of the calculations, the quality of the result and patient treatment plan, the accuracy of

the linear accelerators delivery systems and the overall end-to-end validation that each patient will be treated accurately. But having the intuition and wisdom to detect the potential or underlying problem only occurs with rigorous training. Medical physicists are educated in many important areas and after proper training ideally in an accredited residency program may become certified by the American Board of Radiology, ABR.

Starting in 2014, the ABR will only allow physicists who have completed a residency program to sit for the Boards. This will raise the bar for the exam, thereby raising the competency of all medical physicists in the very near future. But the ABR has to wait until 2014 to allow the growth for the number of accredited programs for this to take place. The growth has been hampered by lack of funding. There are some funding mechanisms but the most assured and balanced method would be for the Center for Medicare Services to provide reimbursement for training physics residents similar to the method that is in place for training physician residents.

And finally, there is an ironic situation regarding oversight of radiation treatment equipment. To operate a mammography unit and to be reimbursed for the procedure, a robust quality assurance program must be in place with oversight by a qualified medical physicist and most importantly programmatic overview by the FDA and the American College of Radiology. This model of requiring a quality program and qualified personnel to be in place with a review by an agency in order to be reimbursed for providing radiotherapy treatments should strongly be considered for radiotherapy as a profession. In closing, approximately a million patients per year are safely and accurately treated with radiation therapy, receiving outstanding and vital treatments but further steps to ensure patients' safety can and must be made.

Thank you.

[The prepared statement of Mr. Klein follows:]

Testimony to the Subcommittee on Health of the United States House Committee on Energy and Commerce

Topic: Medical Radiation: An Overview of the Issues.

Date: February 26, 2010

Eric E. Klein, Ph.D.

Mr. Chairman and members of the committee,

My name is Eric Klein. I am a Professor of Radiation Oncology at Washington University, and have been a Clinical Medical Physicist for 28 years. Over this time period, I have seen dramatic changes in terms of our profession's capability to diagnose and treat cancer. I doubt if any other medical discipline has experienced technological advances to the degree Radiation Oncology has. Our ability to image patients with modalities, such as CT, MRI, and PET, allows us to visualize tumors and involved lymph nodes with millimeter accuracy. We can now customize how doses are delivered to tumors by performing sophisticated calculations, allowing physicians to escalate dose to increase cure rates. Simultaneously, we can reduce doses to critical organs, even those close to a tumor. This has resulted in reduced toxicity.

The delivery technique of intensity modulated radiotherapy (IMRT), which provides superior treatment delivery customization, comes with an increase in irradiation time by a factor of 2 to 10 compared with conventional radiation therapy. Thousands of hospitals and private treatment facilities all over the country have purchased IMRT machinery, often for competitive purposes, and far too often, without properly trained staff in place.

Hospitals need to ensure staffing levels are adequate, not only in number, but in expertise. There should be hands-on testing methods before therapists are allowed to treat patients, with re-testing on a frequent basis. The training for all staff involved, should include the consequence if something is incorrect. There can be as many as 100 steps for each process, and each step must be understood by everyone, especially those with greatest volatility. We do a good job teaching people what to do and what to watch for, but not the consequence if something is wrong.

Though the anecdotal *reported* rate of errors in radiation oncology is quoted as less than one in ten thousand, there are two problems with this rate. First, it may be inaccurate, as there is no depository, nor statewide mandate for reporting such errors. In most states, hospitals are not obligated to report errors occurring with their linear accelerator. A national depository for anonymous error reporting should be instituted in order for the community to learn from such errors (or 'near misses'). The second problem with the low anecdotal reported error rate, is that it is too high.

Hospitals also need to encourage scheduling patterns to allow for “time-outs” before each treatment begins to allow for cross-checking of all parameters by the therapists. Related to this, the time leading up to the patient’s first treatment, should allow for careful review by the physicist of all parameters to be used.

In addition, the manufacturers’ testing of radiotherapy equipment should include fault and interface testing.

In regards to Medical Physicists, we are the vital interface between the physician’s orders and the eventual treatment. We are responsible for; the accuracy of the images used for planning, the validity of the calculations, the quality of a resultant patient treatment plan, the accuracy of the linear accelerator’s delivery systems, and the overall end-to-end validation that each patient will be treated accurately. But, having the intuition and wisdom to detect a potential or underlying problem only occurs with rigorous residency training. Medical Physicists are educated in many important areas including quality assurance and radiation safety, and after proper training, ideally in an accredited residency program, may become certified by the American Board of Radiology (ABR).

Starting in 2014, the ABR will only allow physicists, who have completed a Residency Program, to sit for the Boards. This will ‘raise the bar’ for the exam, thereby raising the competency of medical physicists in the very near future. The ABR has to wait till 2014 is to allow growth in the number of accredited residency programs, which is hampered by lack of funding. There are some funding mechanisms, but the most assured and balanced method, would be for the Center for Medicare Services to provide reimbursement for training Physics Residents similar to the method in place for Physician Residents.

And finally there is an ironic situation regarding oversight of radiation treatment equipment. To operate a mammography unit, and be reimbursed for the procedure, a robust quality assurance program must be in place, with oversight by a qualified medical physicist, and most importantly programmatic overview by the FDA and the American College of Radiology. This model of requiring a quality program and qualified personnel to be in place, with review by an agency, in order to be reimbursed for providing treatments, should be strongly considered for radiotherapy.

In closing, approximately a million patients per year are safely and accurately treated with radiation therapy, receiving outstanding and vital treatment. But further steps to ensure patient safety, can and must be made.

Mr. PALLONE. Thank you, Dr. Klein.
Dr. McCollough.

STATEMENT OF CYNTHIA H. MCCOLLOUGH

Ms. MCCOLLOUGH. Thank you. I do have some visual aids for some of the points.

I want to thank you very sincerely for having this meeting today. It is an honor to be here and I want to speak to you about the safety of x-ray computed tomography most commonly referred to as CT scanning. Next slide, please.

[Slide]

I would like to begin by reviewing the difference between the dose levels from radiation therapy and from diagnostic imaging. On the right there at the extreme high doses such as what is required to effectively treat cancer, radiation can cause severe biological effects. In this high dose region the effects are predictable based on the dose that is delivered and can result in cell death, skin injury, skin reddening, hair loss. Next, please.

[Slide]

In contrast, let's look at medical imaging which uses a factor of 1000 times lower radiation doses. At the doses used in medical imaging, there is a chance an effect might occur but there is considerable controversy about the level of risk in developing a cancer from these low doses. Next.

[Slide]

In fact if we look at the risk levels, the blue line here is a relative risk of one meaning no increase in risk, and the vertical lines on the data points are error bars or uncertainties. The National Academy of Sciences report on the Biological Effects of Ionizing Radiation and the Health Physics Society state that these uncertainties, these error bars do not support making any risk estimates below approximately 100 millisievert. A CT dose is about 10 milliSieverts. In this range below 100 milliSieverts, the risk is either so small or zero but it is impossible to definitively measure. Next, please.

[Slide]

So with regards specifically to CT technology, modern systems are equipped with feedback systems that will monitor the amount of radiation passing through a patient and reaching the detectors and then to adjust that radiation output throughout the patient and throughout the scan to adapt the amount of radiation so you get the image quality that is needed at the lowest dose. These systems automatically adapt the dose across within the patient but across the spectrum of patient sizes from children all the way up to morbidly obese patient. So here is an example of an automated setting taking the dose from the adult level which would be about 165 and it tailored it automatically down to a child level. Next, please.

[Slide]

I would also like to point out that the patient dose for a single CT exam of the abdomen, chest or pelvis is a factor of two or three times lower now than it was two decades ago. The current technical innovations continue to drive doses lower. Next, click.

[Slide]

Even though throughout the years the image quality keeps getting better, these numbers here the section width is the thickness represented by one image and we continue to get thinner which gives higher detail, better image quality. However, CT is a sophisticated medical device and as with any device or procedure human errors or electrical mechanical errors can happen and that is why I am very grateful for the interest of the committee, the FDA and the whole imaging community in ensuring that medical imaging is performed as safely as possible whether or not the exams involve ionizing radiation. Next, please.

[Slide]

I believe that the technology is not our fundamental problem. I believe that the concern is of education for the technologists that operate the equipment, the medical physicists who test the equipment optimizing it, and the radiologists who prescribe the exam protocols. The education has not been able to keep up with the rapidly growing changes in technology and the single most important factor to make this more safe for our patients is to ensure that all personnel involved in operating medical imaging systems meet nationally prescribed minimum levels of training and competency. The needed accreditation and certification programs already exist but without mandatory requirements for a consistent level of education we are allowing in some cases inappropriately trained personnel to operate some extremely advanced medical equipment. Next slide.

[Slide]

One of the examples of the educational efforts being made by the imaging community is a Dose Summit by the American Association of Physicists in Medicine and we are having this in April of this year. We organized this to teach users how to adapt the scan protocols to make sure that they are appropriate for the diagnostic task and for the specific patient. The faculty and attendees includes physicists, radiologists, technologists and regulators, and the meeting is being contributed to by a large number of professional organizations in the imaging community. Of note, the registration is capped at 200 participants and the meeting was sold out within 1 week of registration going live. Next slide, please.

[Slide]

So in summary, today's medical imaging as you have heard and you are well aware has some absolutely amazing technology. It can non-invasively diagnose and guide treatment for injuries and diseases that couldn't be accomplished in any other way. Without CT there would be more unnecessary surgeries such as for suspected appendicitis that didn't turn out to be appendicitis, more invasive diagnostic tests and less effective treatments.

Before the advent of CT, exploratory surgery was not uncommon. But clearly, medical tests whether it has ionizing radiation or not should only be performed when they are medically appropriate. When they are, the benefit far outweighs any potential risk. In fact, there is a very real risk to the patient's health if the necessary medical information is not obtained.

Unfortunately, right now the patients are being frightened by the media reports about the dangers of radiation. We are seeing patients come into the clinic with symptoms of potentially severe ill-

ness or needing lifesaving surgeries or treatments who have refused their CT exam because they have heard on TV or in the papers about this cancer causing stuff. They are being harmed because of not getting the needed medical information.

Mr. PALLONE. I am going to ask you to wrap it up only because I know some of the members aren't going to be able to stay.

Ms. MCCOLLOUGH. OK, I am on my closing right here.

So patients and loved ones, I think, shouldn't be concerned about whether or not the imaging exam is being done properly. We should take care of that with training. They should be concerned about whether they need it.

When my 11-year-old daughter ended up in the emergency room an ultrasound showed a potentially lacerated spleen. They went to CT for the definitive diagnosis. It was normal thankfully and I don't think that was an unnecessary exam. It saved us from having unnecessary surgery.

Thank you.

[The prepared statement of Ms. McCollough follows:]

Medical Radiation: An Overview of the Issues

House Energy and Commerce Committee, Subcommittee on Health
February 26, 2010

**Oral Statement from Cynthia H. McCollough, Ph.D.
Professor of Radiological Physics
Mayo Clinic, Rochester, MN**

Mr. Chairman and Members of the Committee,

I want to thank you - honestly and very sincerely - for holding these hearings today. It is an honor to be here and to speak to you regarding the safety of x-ray computed tomography, which is more commonly referred to as CT scanning.

I would like to begin by reviewing the differences between the radiation dose levels used in diagnostic imaging versus from radiation therapy. At extremely high doses, such as what is required for the effective treatment of cancer, radiation can cause severe biological effects. In this high dose region, the effects are predictable based on the dose delivered, and can include cell death, skin reddening and hair loss.

In contrast, medical imaging uses 1000 times lower doses of radiation. At the low doses used in medical imaging, there is a chance an effect might occur, but there is considerable controversy about the level of risk of developing a cancer from these low doses. In fact, the National Academy of Sciences report on the Biological Effects of Ionizing Radiation and the Health Physics Society state that the uncertainties in the data do not support making any estimates of risk in this region. The risk is either so small as to be nearly impossible to definitively measure, or the risk is zero.

With regard specifically to CT, modern systems are equipped with feedback systems that monitor the amount of radiation passing through the patient and reaching the detectors, and then adjust the radiation output to deliver the required level of image quality using the lowest possible dose. These systems automatically adapt the dose to differences in patient size, both within an individual patient and across the full spectrum of humanity, from newborns to morbidly obese patients.

It is important for to realize that the patient dose for a single CT exam of the chest, abdomen, or pelvis is a factor of 2 - 3 times lower now than it was approximately 20 years ago. And current technical innovations continue to drive the dose even lower.

However, CT is a sophisticated medical device. And, as with any medical device or procedure, both human and electrical/mechanical systems can fail. That is why I am incredibly grateful for the interest of this committee, the Food and Drug Administration, and the imaging community in ensuring that medical imaging is performed in as safe a manner as possible, whether the exams involve ionizing radiation or not.

The technology is not, however, our fundamental problem. Rather, education and training of the technologists who operate the equipment, the medical physicists who test and optimize the equipment, and the radiologists who prescribe the exam protocols has not kept up with the rapid developments in the technology. The single most important contribution we can make to patient safety is to ensure that all personnel involved in the operation of CT systems meet nationally-prescribed, minimum levels of training and competency. The needed accreditation and certification programs exist, but without mandatory requirements for a consistent level of advanced education, we are allowing, in some cases, minimally-trained personnel to operate extremely advanced medical equipment.

As one example of the numerous multi-disciplinary efforts being made to ensure patient safety through education, the American Association of Physicists in Medicine is holding a CT Dose Summit in April of this year. We organized this meeting specifically to teach users how to be sure that the scan protocols used are appropriate to the specific diagnostic task and the specific patient. The faculty and attendees include medical physicists, radiologists, technologists, and regulators. The meeting is endorsed by a large number of professional societies, and received educational grants from the National Institute of Biomedical Imaging and Bioengineering, the American College of Radiology, and the Medical Imaging Technical Alliance. We will offer repeat presentations at any society meeting that will have us, and we will repeat the Summit as long as demand continues. This is but one example of the many educational and quality initiatives from the imaging community.

In summary, today's medical imaging uses some absolutely amazing technology and can non-invasively diagnose and guide treatment for injuries and diseases that could not be accomplished in any other way. Without CT, there would be more unnecessary surgeries, such as for suspected appendicitis that turned out to not be appendicitis, more invasive diagnostic tests, and less effective treatments. Before the advent of CT, exploratory surgery was not uncommon.

But clearly, medical tests, with ionizing radiation or not, should only be performed when medically justified. When they are medically appropriate, the benefit far outweighs any potential risk. In fact, there is a very real risk that the patient's health will be harmed if the necessary medical information is not obtained through the appropriate imaging exam. But, unfortunately, patients are being unnecessarily frightened by media reports about the danger of radiation at the dose levels associated with CT. We are seeing patients come to us with symptoms of potentially severe illnesses or needing life-saving surgeries who are refusing CT exams, because they have heard on television or read in the paper about that "cancer-causing stuff," even though the standard of care would be to have a CT exam. The reality is that the risk of radiation injury from a CT scan is virtually non-existent. Patients and their loved ones should be concerned only about whether or not an imaging exam is needed to help the physician make the best possible diagnosis and treatment decision. If the information is of potential benefit to that patient's medical care, then the patient should absolutely proceed with having the CT exam.

When my 11-year-old daughter fell from a bunk bed and landed on the edge of a piece of furniture, the portable ultrasound scanner in the emergency room showed a large, ominous shadow consistent with a lacerated spleen. Because ultrasound imaging can "be fooled" and her condition was stable, a CT was recommended - to give us a definitive diagnosis. I did not hesitate to agree to the CT examination. Thankfully, the CT was negative, showing no abdominal injuries. I do not consider that CT exam, even though it was "normal," to be unnecessary. Rather, I consider it to have been invaluable, as it avoided unnecessary emergency abdominal surgery.

Thank you for allowing me to share this information with you, and for taking the time and interest to consider the best interest of our patients.

As a supplement to my oral testimony, I include here additional information for your consideration.

Radiation Dose and Safety During Computed Tomography

In general, the radiation dose levels from most diagnostic medical imaging examinations, including CT, nuclear medicine, and fluoroscopy, may increase a patient's risk of a fatal cancer by only fractions of a percent. This can be compared with the background rate of a fatal cancer in the U.S., which is about 22%. Because the potential risks are so small, there is considerable uncertainty as to the exact numerical value of risk at the low dose levels associated with medical imaging and prudent assumptions are made to assign this value that are consistent with the existing data so that the medical community may have some guidance when making risk/benefit decisions. The risks may, however, be zero.

Radiation induced cancers can not be distinguished from cancers caused by other sources, and the cancers can take from years to decades to occur. Because the risks at the low doses associated with medical imaging are so small compared to at higher doses, definitive observational evidence of increased risk due to medical imaging that uses ionizing radiation is not likely to ever be able to be demonstrated. For the dose associated with a typical cardiac CT or a CT of the abdomen and pelvis, between 1- to 10-million exposed individuals would need to be followed over their entire life to discern any statistically valid increase in risk compared to background cancer rates! Thus, ionizing radiation is at worst case a very weak carcinogen. Particularly in adults, where 85% of CT examinations are performed, the risk of a radiation induced cancer from the naturally occurring amounts of background radiation received each year of one's childhood exceeds the incremental risk from any diagnostic imaging exam received in adulthood.

In light of the very small level of potential risk and the absence of consensus as to whether there is any risk at the low levels associated with medical imaging, why is the concern about cancer from CT exams, for example, so great? The answer is primarily because of the large numbers of CT exams performed each year (an estimated 60-70 million exams per year in the U.S.). The concern is amplified by the generally held perception that radiation is extremely dangerous, the lack of familiarity with radiation units and effects, and the tendency to underestimate risk associated with more familiar behaviors. The risk of death by drowning is greater than the risk of death from a cardiac or body CT exam, yet the CT exam is widely perceived as having a much higher risk.

What then is a rationale response to concerns regarding the radiation associated with medical imaging exams such as coronary angiography, body CT, or radionuclide imaging? First, steps must be taken to ensure that exams are medically justified. Even a small amount of risk, as may be the case for medical imaging, is inappropriate if there is no anticipated benefit. Secondly, steps to keep doses as low as possible, such as dose

reduction technology, accreditation programs, and improved user training must continue to be a high priority throughout the medical imaging community. Much progress has been made in radiation dose reduction and dose management techniques over the last decade, but best practices in the field of dose management must be dispersed across the spectrum of practice types and sizes.

Modern CT systems, and by this I mean systems manufactured within the last 5 or so years, are equipped with sophisticated software algorithms that automatically adjust the amount of radiation coming out of the scanner according to the size and shape of each particular patient and according to the diagnostic imaging task. The systems know how to dial down the radiation output and how to increase the radiation output for obese patients. Systems are also able to automatically adjust the acceptable level of image quality according to the type of examination the physician prescribed. Low-dose CT scans of the chest or colon for cancer screening produce extremely noisy images that are nonetheless highly accurate at seeing soft tissue lesions against a background of air. Other examinations, such as CT exams of the small bowel to detect very small amounts of bleeding in the small bowel, for exams to detect small and subtle cancerous liver lesions, require images of much higher quality. All current systems allow the user to select from a variety of protocols according to the individual needs of the specific patient.

The imaging community, including the manufacturers and professional societies, has been actively engaged in a quest for lower and lower doses, and as a result, modern CT exams use doses that are factor of 2 or 3 lower than in the 1980s and early 1990s. Not only are the doses lower, but the image quality is much, much better. Instead of 10 mm thick slices of anatomy, images representing thicknesses of less than 1 mm are routinely available. Instead of performing several overlapping scans to allow the patient to take a breath every so often during the exam, current scanners can scan a 6-foot adult from head to toe in less than 20 seconds. The downside of these tremendous advances in technology is the difficulty in maintaining adequate training in such a rapidly-changing field. Professional organizations offer continuing education courses and special sessions on advances in dose reduction methods at numerous times through any scientific meeting.

In April of this year, I will be co-directing a CT dose summit that is sponsored by the American Association of Physicists in Medicine and is financially supported by the American College of Radiology, the National Institute of Biomedical Imaging and Bioengineering, and the Medical Imaging Technology Alliance. It is co-sponsored by the Radiological Society of North America, the Health Physics Society, the Conference of Radiation Control Program Directors, and the American Board of Radiology Foundation. AAPM organized this meeting as a direct response to the reports of overexposures for neuro CT perfusion scanning in just over a month's timeframe. Registration is capped at 200 participants, and we sold out after only one week of open registration. I point to this as an example of the engagement of the medical imaging community in providing education related to CT dose management.

What is the typical radiation dose associated with CT?

Today's CT scanners use a much lower dose of radiation than was used even 5 years ago. This is a result of recent concerted efforts by imaging scientist and manufacturers of imaging equipment to decrease the radiation doses associated with CT imaging. The dose used in a CT examination is now tailored specifically to each patient's body size and the diagnostic questions being asked. Particularly in pediatric patients, the imaging community clearly understands that a "one dose fits all" approach is not appropriate.

The risk of radiation exposure from a medical imaging examination, often expressed in terms of effective dose, should be put into proper perspective. The increased risk of a fatal cancer from a 10-mSv cardiac CT or abdomen/pelvis CT examination is very small. Some data suggest that at such low doses, there is actually no increase in cancer risk. However, to err on the side of safety, a non-zero risk is assumed for any radiation exposure, no matter how small, with the risk increasing linearly with the effective dose.

Using the most current consensus risk estimates from the National Academy of Sciences, the risk of death from a 10-mSv cardiac or abdomen/pelvis CT is lower than a person's lifetime risk of drowning (0.9 in 1,000) or being killed after being hit by a vehicle while walking (1.6 in 1,000).

The radiation doses associated with a CT examination ($\approx 1-14$ mSv) depend on the specific equipment and examination type. This range of doses is comparable to the dose received annually from naturally occurring sources of radiation such as radon and cosmic radiation (≈ 3 mSv per year). However, depending on the elevation and soil type where a person lives, the amount of naturally occurring (i.e., background) radiation can vary from 1 to 10 mSv.

Some communities with very high background levels of radiation have been extensively studied for carcinogenic effects from ionizing radiation. Interestingly, these population groups have a decreased cancer rate relative to similar communities in which the background radiation level is much lower. In some parts of the world, background radiation levels are 10 to 400 times higher than the typical background in the United States, yet no increase in the frequency of cancer has been documented in populations living in these areas of high natural background radiation.

When should CT be used? How does the radiation dose from CT compare with that from other imaging examinations?

CT examinations should be performed only when the expected information from the examination has a potential clinical benefit to the patient. The American College of Radiology has professional guidelines detailing the appropriateness of a CT examination for

various symptoms or conditions. Compared with magnetic resonance imaging, CT is a much quicker examination and has far fewer patient contraindications (e.g., implanted electronic medical devices such as pacemakers). Relative to ultrasonography, CT has much better spatial resolution, is a quicker examination, and has minimal variability in image quality due to different skill levels of the imaging technologist or sonographer. Hence, CT is frequently considered the first-line recommendation when diagnostic imaging is required.

The radiation dose from a CT examination is similar in magnitude to that from nuclear medicine examinations, such as cardiac stress testing, or from some fluoroscopic procedures, such as invasive angiography. It is important to remind patients that although CT does involve more radiation than conventional radiography, it also provides much more information. For example, a chest CT scan can image a thorax in a few seconds with submillimeter resolution. From this one scan, hundreds of images can be produced for detailed views of a patient's anatomy. Such detailed information allows for making more rapid and accurate diagnoses and more efficient and effective treatment decisions than is possible with standard radiography.

What is being done to decrease the radiation dose received during CT scans?

First, CT scans are optimized to use doses as low as reasonably achievable without compromising the diagnostic task. The most basic step to minimize radiation dose for a medically justified examination is to adjust the technique factors to ensure that the right dose is delivered based on the patient's size (attenuation) and the specific diagnostic question. This is considered the current standard of care in CT imaging. In some cases, this may mean that increasing the dose is the most appropriate action (e.g., in obese patients or those with traumatic injuries).

Since the mid 1990s, automated exposure techniques have been used to further tailor the dose used in CT examinations to the specific patient and diagnostic task. These sophisticated systems automatically set the dose to the lowest appropriate level. These automatic exposure control systems can lower patient doses substantially, typically by 20% to 50%. In addition, as CT technology has progressed, the dose inefficiencies of earlier multislice systems have been resolved.

In the 1980s, 10-mm wide images and multiple breath-holds were considered state-of-the-art in body CT imaging. Now, a 5-mm image width and a single breath-hold is considered routine, with 2- to 3-mm image widths used for many applications (e.g., CT enterography or angiography); reconstructions of 1 mm or less are routinely used for multiplanar reformations (e.g., coronal or sagittal views) or 3D surface or volume renderings. Thus, today's CT systems provide thinner image widths with improved spatial and low-contrast resolution at a fraction of the scanning time and patient dose used just a decade ago.

Key Facts

- Every day, people are exposed to ionizing radiation from many naturally occurring sources such as radon gas in the home, radiation from outer space, radiation in rocks and soil, and naturally occurring radioactive elements in the body (e.g., small amounts of radioactive potassium are present in the human body).
- After a computed tomography (CT) study, no radiation remains in the body. There is no limit placed on the number of CT images a person can have. Each scan should be justified by the current medical situation.
- CT may be ordered in pregnant patients if the mother's medical condition requires imaging to make an accurate diagnosis or guide treatment. Even from a CT examination of the abdomen and pelvis, the radiation exposure to the fetus is considered negligible. In a woman who has not been exposed to ionizing radiation, the probability of the baby having no congenital malformations or defects is approximately 96%; a CT scan directly over the fetus, even with multiple contrast phases, changes the odds to approximately 95.99%. In fact, no diagnostic imaging examination delivers a high enough dose to the fetus to consider termination of the pregnancy.
- A report on sources of ionizing radiation in the United States (NCRP report No. 160, titled "Ionizing Radiation Exposure of the Population of the United States"), caused many people concern about increased radiation doses from CT scans. Although the use of CT has increased considerably in the past decade, the dose per examination is decreasing. There is no increased risk to the population in general, since only those receiving a medical exposure incur any potential increase in risk. It is essential to remember that the increased use of CT is due to the increased number of clinical applications for which CT now is the most appropriate diagnostic tool.

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Mr. PALLONE. Thank you, Doctor, and I agree with you.

I am going to pass and have Ms. Eshoo go first because I know she has another commitment.

Ms. ESHOO. Thank you, Mr. Chairman. It is called the commute to California, hopefully getting the plane but I didn't want to leave you.

First, I want to thank each of you, the witnesses starting with Mr. and Mrs. Parks. I am a parent and it just should not be the case where parents bury their own child so what you have done in coming forward today is enormously helpful to us, and it is painful for you but I think that what you are doing in the name of your son is an enormous contribution for us to really address and get to the heart of what has happened, and that would be the greatest tribute to him so I want to thank you. And to Ms., is it Lindley? I think that you articulated so well what these technologies bring forward and the hope that they represent, and your own example, and by no means does anyone on this committee want to put a dent in what we have produced in our country and that is in so many cases second to none in terms of the application of the technologies that are lifesaving and life-extending, and I think that what you said really points to that. To the professionals, to the doctors that are here, it is wonderful to have someone from our region from UCSF, absolutely terrific.

Let me just make a couple of observations. We have, it seems to me in looking at all of this that we have safety procedures and oversight that need to be addressed, that we have obviously 50 States and we have a patchwork quilt of regulations. There isn't any consistency that I can find in terms of what I have read. There is the whole issue of proper supervision. Radiation is lifesaving and it can kill someone so I mean this is something that needs to be supervised and there has to be proper supervision but there also has to be education and training in this, and we don't really have any national standards on that. One of the doctors mentioned the practice variations that exist and there are really no standards across the manufacturing field. Accreditation, I mean I don't think there is any national standard relative to accreditation. What I am stunned by is that there aren't more cases that other than Mr. and Mrs. Parks coming in. Thank God but this has really sent up the red flag.

So what I would like to ask is of the professionals, of the doctors, A, would you recommend national standards in these areas? I can't help but think of the Mammography Quality Standards Act that one of the staffers and it is in our staff report here that many years ago we were facing with mammography and the Congress stepped up and put that law on the books and it addressed many of the issues that we are talking about here today.

Do any of you disagree about national standards needing to be addressed? So you all agree.

Do you believe that there should be accreditation in this area and licensure of those that administer the radiation?

Ms. MCCOLLOUGH. In CT, the American College of Radiology has an accreditation program that is not mandatory by regulators but has become mandatory in a de facto sense because the insurance companies started requiring it in order to get reimbursed, and so

the program actually has thousands of units that are accredited. The program does address those. We measure those. We have a database of those and as part of that accreditation program, I have seen it continue to raise the bar of quality in CT since its inception in 2001.

Ms. ESHOO. Now, what again from the doctors, what responsibility do you believe the manufacturers have in this? What positive role can they play? Where do you—I mean maybe this is a sticky wicket for you to be telling us but I am not on a hunt against anyone but it seems to me that we have got to examine each facet of this and if you think that there is an important role for them to play in this and what that would be.

Dr. SMITH-BINDMAN. I think in the area of diagnostic medical imaging we have very little data about what is currently going on.

Ms. ESHOO. What does that mean, going on?

Dr. SMITH-BINDMAN. It means that Dr. McCollough told us that a CT scan has a dose of 10 milliSieverts. When we went and collected dose information, in fact the doses were two to threefold higher than that on average and for one patient the doses ranged for one type of problem ranged from five to 100 milliSieverts for the kind of test that is supposed to have a dose of 10. So in fact we don't know what is currently going on. The doses in general could be much higher than we think and more variable. Part of the problem is there is no organization collecting those, documenting those and part of the difficulty in that is the standards for reporting those vary across the board. So there is no consistent way that dose is reported that a radiologist could easily look at the information on an individual scan and understand. So you asked about the role of the manufacturers. There are several very important committees that over the last several years have agreed upon standards for reporting dose information, for putting that information in the medical records. These standards have not been adopted by the manufacturers. If these standards were adopted by the manufacturers, we could quickly know what is going on and then determine how closely different facilities abide by those guidelines that we would put out there. So we need guidelines about what is allowable and we need data to decide if places are within those guidelines so I think the manufacturers could enormously move this field forward by adopting these standards immediately and having this data available.

Ms. ESHOO. That is very helpful. I know they are going to testify at the on the next panel but I won't be here and we definitely need to work with them.

Dr. Klein, did you want to add to that?

Mr. KLEIN. I would rather have Dr. McCollough respond.

Ms. ESHOO. OK, great and then I will yield back.

Ms. MCCOLLOUGH. I do have a slightly different perspective on this. There is an organization called the International Electrotechnical Commission and it is a trade organization that is worldwide that the U.S. participates in through the National Standards Institute and that organization, the IEC, actually sets very well-prescribed standards about how the radiation output of a scanner is to be measured and the scanners effect in Europe can't even be published with some of these. So in the U.S. we have the same IEC

labeling if you will, on all our standards and the value of the dose output of the scanner is actually shown on the console. It is mandatory that it be shown.

Ms. ESHOO. Well, who reads that?

Ms. MCCOLLOUGH. It is right in front of the technologist.

Ms. ESHOO. They do read that before they use it, really?

Ms. MCCOLLOUGH. It is in front of them and one of the things is the protocols tend to be prescribed for a given patient and diagnostic task, and the variation that you are hearing about radiation gets stops kind of quickly in tissue so every four centimeters of extra-thick that a patient is, you need to actually double the machine output to get the same image quality. So from a thin, perhaps Asian woman to an obese patient that is a factor of 64.

Ms. ESHOO. Yes, I have to tell you, I mean you are absolutely brilliant. You know this better than anyone. That is why you are one of the expert in terms of testifying but to suggest that the knowledge is somehow transferred through the system because there is a sticker or something on the equipment doesn't do it for me. I have to say that but thank you very much, Mr. Chairman, and this is going to require some work of our committee but it is what we are here for. And I think that with the people that you have assembled, and we need all of you to be part of the, I am sure legislation that we will draft and pass, and it should be bipartisan. This is something that knows no partisanship because it could be me. It could be you. It could be anyone of us so thank you very, very much.

Mr. PALLONE. Thank you, Ms. Eshoo.

You can continue, Dr. Klein.

Mr. KLEIN. Well, in regards to radiation oncology equipment and manufacturing responsibility it certainly the machinery goes through quite a bit of testing as when it is in the factory and as it gets delivered. What could be done better is the training for the users, fault training to demonstrate if this message shows up this is exactly what it means and some of the manufacturers are inconsistent on some of the testing that they perform with the users, with the physicists. One company does a very good job, for example, of forcing errors to happen and then watching that the machine will stop and show you what that error is but it is not consistent. And the other problem that is a wide variation is problem reporting. How errors or how machines that aren't functioning properly, how that information gets to all the users. It varies again how we get that information. Unfortunately, sometimes it is anecdotal or list servers, rather than direct communication to any potential user of this equipment. It might be better to do overkill communication right now which is scant and irregular. Thank you.

Mr. PALLONE. Thank you.

Mr. Whitfield.

Mr. WHITFIELD. Mr. and Mrs. Parks, I also want to thank you for being here today and sharing your son's ordeals with us. We appreciate that and, Ms. Lindley, thank you for being here, as well.

When we talk about medical imaging, it is rather limited. I mean we talk about CAT scans, MRIs, x-rays and that is primarily it but then when we talk about radiation therapy I am assuming that there, would there be hundreds of radiation therapies or I know

that we have linear accelerators. We have Gamma Knives. We have—Dr. Klein, would you help me with that about the different kinds of radiation therapy?

Mr. KLEIN. Sure, the main core of patients are treated with linear accelerators which come in some differences. There are the far majority come in machineries that can deliver what are called photon, means deep-penetrating and maybe with or without being called electrons which are not so penetrating. And then there are very customized treatment delivery equipment with external beams such as was mentioned by Ms. Lindley as Cyberknife and Gamma Knife which are very specific for specific sites. There is also the use of actual radioactive sources directly placed in the tumor for a technique called Brachytherapy which again was what happened with the VA hospital was a form of Brachytherapy. So there are variations but the core of patients are treated with linear accelerators.

Mr. WHITFIELD. Yes, oK, and when we talk about beads being placed, what is that?

Mr. KLEIN. Those would, I am sure certain that those must have meant radioactive seeds which are placed in the tumor.

Mr. WHITFIELD. OK.

Mr. KLEIN. Sometimes they are given over a few days or 5 days or sometimes left in permanently.

Mr. WHITFIELD. OK, well, let's take a linear accelerator for just a moment. Of course, we have the manufacturer involved because they made it. Typically, how many people would be required to be on the site when the linear accelerator is being used as it was on the Parks' son?

Mr. KLEIN. I would say for the most part two radiation therapists are at the console. There can be three, hopefully, not one although I have witnessed that on some occasions.

Mr. WHITFIELD. So two radiation therapists?

Mr. KLEIN. Yes.

Mr. WHITFIELD. Now, are radiation therapists medical doctors?

Mr. KLEIN. No, the word therapist does throw people off. These are radiation technologists who have had the education to become radiation therapists in treating patients but they go by the name therapist.

Mr. WHITFIELD. Well, I know that from reading about Mr. and Mrs. Parks' son, it appears that his injury was sustained because of the filters. The filters were not calibrated or adjusted in the proper way.

Mr. KLEIN. What happens with regulator radiation therapy conventional is that there is an opening beam that treats a patient. With Intensely Modulated Radiation Therapy, there are devices, a little culmination devices that move in and out of the beam which gives it this very customized way of delivering therapy and so if those aren't in place, then the results can be problematic and I am sorry, and that is because of the irradiation time. The time it takes to deliver IMRT, as I mentioned in my testimony, is longer than conventional therapy because the beam for the most part is being blocked so it creates extra time.

Mr. WHITFIELD. Right, right, well, from the testimony, you all can correct me if I am wrong but it appears that the recording of errors, the doses being used, the sharing of information to the peo-

ple that should know it, it appears to be really a fragmented system that I am assuming would vary greatly with every institution. Would I be correct in that assumption?

Mr. KLEIN. It certainly would. An institution does from institution to institution is how they handle errors, what type of database they have and how they examine and report back to the entire staff I know will vary considerably.

Mr. WHITFIELD. Yes.

Mr. KLEIN. And then obviously from State to State and so forth.

Mr. WHITFIELD. Well, you know, I am really glad we are having this hearing because all three of you have indicated that you do feel like there does need to be some national standards to assist in this area, and when we are dealing with equipment like this that can certainly provide healing powers and do miraculous work, it can certainly destroy a person as well, so your testimony has really been helpful and I do thank you all three of you for being here.

Let me ask Dr. McCollough one question just out of curiosity and now this isn't anything technical but I noticed that either in your testimony or in your resume that it talks about College of Medicine, and I wasn't, I guess I should have been aware but I wasn't even aware there was a College of Medicine and Mayo Clinic. I mean I know you have residency programs.

Ms. MCCOLLOUGH. We have a medical school, also.

Mr. WHITFIELD. There is a medical school.

Ms. MCCOLLOUGH. Yes and that is where our academic appointments.

Mr. WHITFIELD. And how many students do you have there?

Ms. MCCOLLOUGH. I don't know offhand. It is a relatively small class size, probably 50 to 100.

Mr. WHITFIELD. So this would be interns or residents or undergraduates or all three?

Ms. MCCOLLOUGH. Well, the medical school is to train physicians.

Mr. WHITFIELD. Right.

Ms. MCCOLLOUGH. The residencies would be physicians in their specialty training, and we have Ph.D. programs, and we train technologists and allied health.

Mr. WHITFIELD. OK, so you have the whole gamut then.

Ms. MCCOLLOUGH. We try.

Mr. WHITFIELD. OK, thank you.

Mr. PALLONE. Thank you, Mr. Whitfield.

I am going to ask some questions now. I wanted to first again I don't know how I could thank the Parks' enough for being here and, you know, for relating the story of your son. It is just really a sobering reminder of, you know, why we are here today, frankly, that you are relating to us.

I just wanted to ask Mr. Parks, you mentioned the error reporting, why is that so important, if you would. You mentioned the error reporting, you know, that when they report the errors you mentioned that. Why do you think that is so important, the reporting? Again, I got to ask you to turn that, yes.

Mr. PARKS. My understanding is these machines have like a focus and ordinarily it seemed to me they should be shut so that they can over, they can't kill anybody but in this case it was wide

open and it was wide open at 3 days in a row where the physicist didn't check the machine. Nobody did and in the little we know about it, there were four unauthorized, untrained people who fiddled with that machine during those 3 days, and that I can't explain that. I don't know why that happened.

Mr. PALLONE. OK, so your view you are basically saying is that if there was more supervision and these things were reported then we might prevent it.

Mr. PARKS. Yes, the physicist, it is our understanding, was gone. She went somewhere to a meeting or to a seminar or something, and left. There was no one else qualified there. They should not have run the machine if there is nobody can run it but they did, and there needs to be enough staff to where there is somebody all the time watching that machine. Also, we found that the ones that were there were watching the monitor, and apparently it give them some sort of a medication that makes patients vomit sometimes, and his face was covered with a mask and they were watching to make sure he didn't vomit into the mask and aspirate. They weren't watching the monitor that was telling them that something is wrong but they didn't look at it. They didn't look at the monitor and he didn't vomit, of course, but there was just inattentiveness there.

Mr. PALLONE. OK, thank you, thank you so much.

Ms. Lindley, you know, I think it is I mean obviously you said and I have said that it is critical that these technologies be available but you also, do you also think that more needs to be done to make them safer? Maybe let me get the mike again there.

Ms. LINDLEY. I have been in pretty safe hands and I think that especially with Selective Internal Radiation Therapy that I had which was they implanted radiation they did after I had the procedure they actually took me back and did a spec scan to ensure that the radiation was in my liver and that everything was good, and so with it I was very confident. After I read their article, I know that the next time I have a treatment that I will definitely ask more questions and I think that it is good to be proactive.

Mr. PALLONE. All right, thank you so much.

Let me ask the three doctors, I know time is running out here but I wanted to ask the three doctors a question and this gets a little complicated but if we look at ways to improve the system there are two major models that I know of. One is the Mammography Quality Standards Act which I guess I will call MQSA and then there are changes in the Medicare Improvement for Patients and Provider Act which is MIPPA, I guess. I hate to use these acronyms but I have no choice, and my understanding is that the MQSA is much more detailed and sort of aggressive. That is sort of a general statement on my part. There is no accreditation required for radiation treatment facilities. No licensing requirement for personnel. So let me start with Dr. Klein, you mentioned the mammography standards in your testimony. I guess that is the MQSA. You know, I believe in the importance of these standards but the question is, you know, radiation therapy too complicated or too diverse for Congress to regulate it the way we are doing with the MQSA? I mean would you think that we could go that route

or do you think that we should just leave it up to the practice of medicine?

Mr. KLEIN. I think because of its complication, complexity it is even more necessary to have oversight and to have accreditation for facilities.

Mr. PALLONE. So you would—would you use the MQSA model?

Mr. KLEIN. Not exactly that model but what it is trying to accomplish, yes, which is uniformity that all mammography centers are giving the lowest doses possible to get the best images, and I think that philosophy should be carried forth that every facility before it turns on a beam has been checked, and the personnel know exactly what they are doing.

Mr. PALLONE. OK, now, can I make a distinction between, you know, the mammography standards, the MQSA, and the MIPPA in your mind and, you know, whether you think one is a better model than the other?

Ms. MCCOLLOUGH. The MQSA model is very prescriptive in terms of the credentials that each member of the health care team needs in terms of the quality assurance program, how frequently it needs to be performed, and in that sense the sort of consensus of the professionals in the community were able to give a set of best practices. I am not familiar as much with the MIPPA but my understanding is that it has not got as in depth and prescriptive credentialing requirements for the staff, for example certainly not going into the detail with the quality assurance.

Mr. PALLONE. So you would be more inclined to use the more detailed or aggressive model of the MQSA. I hate to, you know, I am using my own terms here to describe it but you would be inclined that way?

Ms. MCCOLLOUGH. I think it has been a very good program. Certainly, there is, you know, a lot of overhead that comes with it so we would just want to be very, you know, cautious as we move forward that we, you know, do the best without adding too many levels of extra steps.

Mr. PALLONE. Do you want to comment, Dr. Smith-Bindman?

Dr. SMITH-BINDMAN. I do. A lot of my research focuses on breast cancer so I know the MQSA rules and regulations in detail, and I know the impact they have had on the quality of mammography cannot be overstated. Mammography has improved profoundly since the enactment of MQSA regulation and one of the things that is so wonderful about this is they actually follow what happens at the patient level in terms of what they are likely to get when they go for a mammogram to ensure that it is of a high quality. So I think there is probably a role for both of those in oversight but MQSA has improved both the technical quality of mammography, and it has also improved the interpretation of mammography by having agreed upon standards by which these exams are done and interpreted across the country, and so the impact has been really phenomenal on the quality and improving women's access to high-quality mammography.

Mr. PALLONE. I know I am out of time but let me just ask one more thing since I am on this. Now, CMS is currently implementing the MIPPA standards so I guess one could say, you know,

should we see if they are fully implemented before we, you know, use them as an example?

Dr. SMITH-BINDMAN. I think it is very important to think about what accreditation is going to do, and I think if accreditation is going to put some general standards out there, that is absolutely a move in the right direction but what you really want to make sure is that every patient at every facility is safe and getting the best quality exam they can, and I am not sure that an overview of accreditation will give you that. So I think it is certainly a place to start. It makes no sense to have facilities that are not accredited as long as we make sure that accreditation actually gets a quality. But I think in addition to that we also need some safety measure to make sure that we are actually getting the highest possible quality out of these tests as possible.

Mr. PALLONE. All right, thank you very much.

Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman, and like everyone, I would like to thank all our witnesses and, Ms. Lindley, particularly as I say to my colleagues on the committee, you and I don't have to have an interpreter to talk since we are both from Texas, and but thank you for bringing this up. And I have watched them because some of us have served on the committee for many years and health care is as much a part of my life as it is a physicians, I think, because we, our goal is to expand access and over the last 2 years when we have seen what has happened and, you know, take away that trust that both patients and families have in some of the technology we have, that is what worries me because I look at it, and you all heard in my opening statement that in medical technology we are growing every day in our ability. I know on our next panel is a staff member for M.D. Anderson and I have been there and watched what both as it was being built but also their laser treatment facility there. It is amazing what can be done today that use to couldn't be done simply because surgery couldn't do it, and that is why I am so concerned about making sure we get it right so we don't take away that growth into technology that makes us healthier people.

Dr. Klein, can you describe the latest advances in radiation therapy? And like I said having been to M.D. Anderson a number of times, I know my local one but I know there are also great facilities all over the country.

Mr. KLEIN. As I mentioned before, there are numerous variations on linear accelerators and what has been the most exciting addition to these linear accelerators as the ability, as the addition of imaging devices actually in the treatment room, and this has had a huge impact because now we can capture exactly how the patient is setting up, and for that matter being maintained in the right position during treatment, and this is very important. So this is what is known as Image Guidance Radiation Therapy. So this has helped us improve our accuracy of setup and also how the patients are being treated throughout the course of a given treatment.

The other new technology that is starting to boom, of course, is Proton Radiation Therapy. These are large facilities that deliver a very different type of radiation therapy, very customized and idealized for pediatric radiation therapy, for example.

So these are some of the new things that are coming and nothing should ever stop these from happening, again, but the people trained to use them and how they are used, again, needs to be looked at with scrutiny.

Mr. GREEN. Well, I know there is a difference between radiation that maybe we have all been accustomed to for decades but compared to what is happening today whether it be proton or even hyphenated usage of radiation, could you just talk about that, the difference between what has happened in the last few years on treating particularly cancer?

Mr. KLEIN. Well, being not a physician, I think almost every tumor sites now, and when I mean site I mean by site of the body, has found a way to be treated with radiation therapy more uniquely and customized. For example, not every patient is a great candidate for Intensely Modulated Radiation Therapy. There are some that still benefit from conventional therapy but certainly for the most cases IMRT has improved our ability because a lot of these tumor sites are in locations that happen to be right next to a critical organ that we don't want to give any dose to and lately we have been able to give, again, the curative doses we need to those tumors while not giving the dosage that would cause problems to the organs nearby, and that has only been improving over the last 5 or 10 years.

Mr. GREEN. OK, well, and I know having heard Mr. Parks and, again, what happened to Mr. Parks' son is it just seems like we ought to be able to prevent it but on can we do better on reporting the error although we know there is reporting because otherwise we wouldn't be here today because we see it in lots of different, varying facilities around the country even a VA facility so is it do we need to do better on reporting errors so we can make changes or corrections sooner?

Mr. KLEIN. I always think of error reporting in two flavors. One is anonymous reporting. Reporting that someone sends in an error that it happens with this particular machinery and does an analysis of why it happened but they do it anonymously so that they are more likely to do that because of there wouldn't be any direct liability. Now, the industry learned that that was a great way to go for learning about incidents and near misses too, and not just incidents that happened but ones that almost happened and everyone learns from that. And then, of course, there is the other error reporting for an actual damage to a patient and they sort of both have to happen but again you can learn something from both. But anonymous reporting is something that we use and need to consider, and a lot of facilities are reticent to do so because they are afraid is they can clearly submit an anonymous report without getting into trouble.

Mr. GREEN. Well, and I know from other members' questions on both sides of the aisle that it is not something we may be able to do voluntarily, you know, the industry to regulate itself. It sounds like we actually need legislation to deal with it, is that correct?

Mr. KLEIN. I think that if we go to the step of having error report, every error reported as mandatory then it obviously has to come from an agency. Now, the Nuclear Regulatory Commission does that right now. If you are in a State that is where the isotope

used, use of radioactive materials it is still governed by the Nuclear Regulatory Commission. Not every State has that, two-thirds do not but in Missouri if an error were to happen with use of an isotope for radiotherapy such as Gamma Knife, we absolutely have to report that but if an error happened with a linear accelerator in Missouri, we wouldn't have to report it to anyone.

Mr. GREEN. Well, Mr. Chairman, it sounds like we have some ideas on what we need to deal with on the legislative. Thank you. I know my time has run out.

Mr. PALLONE. Thank you, Mr. Green.

Ms. Castor.

Ms. CASTOR. Well, thank you very much, Chairman Pallone, for calling this important hearing and thank you each and every one of you for being here today.

There have been such tremendous technological advances in medical treatment but along with these advances come increased hazards when the equipment malfunctions or is improperly setup or used incorrectly, and as the equipment becomes more powerful, I think we would all agree that it is imperative that everything possible be done to minimize the risk of something going wrong. And there was a terrible case in my hometown at the premiere cancer center that has a sterling reputation. It is just outstanding but, unfortunately, and this was a few years ago 77 brain cancer patients were over-radiated because a newer, more advanced machine had not been setup correctly. The problem wasn't discovered until inspectors from the Radiological Physics Center, a Federally financed testing service, came in for an inspection, and the director of the Radiological Physics Center said that if the inspection occurred earlier or if the Center had a regular practice which included inspections earlier they—we really could have avoided these terrible errors. So I know you all have called for greater training, broader accreditation but on this narrow topic what about the folks that come in and install? The manufacturers' representatives are they—do they bear some responsibility of catching these errors and doing that testing? Should accreditation programs include the manufacturers' technical representatives? Dr. McCollough, do you want to start?

Ms. MCCOLLOUGH. It is incumbent on the facility to actually have one of their own physicists or a hired physicist or something to test as an independent measure because the equipment manufacturers come and make sure it is operating according to specifications but then there is what I assume happened in this case the secondary test that then that the in-house people measure and calibrate it and set it up for their usage. So I think duplicative systems are always good, checks and balances, and so the manufacturers make sure it is operating. The users then have to make sure they set it up correctly and use it correctly.

Ms. CASTOR. Yes, because according to their in-house tests, it was operating adequately or acceptably, and it wasn't until the Radiological Physics Center came to again that they noted the errors.

Dr. SMITH-BINDMAN. I think that it is very important to know how the machines are used in actual practice, not how they are used before they leave the factory, and the manufacturers when they come in to setup every CT scan for diagnostic imaging, at

least, they work with the local physicians to figure out how to setup those scans. And it turns out it is a complicated topic but you get prettier pictures if you turn the dose up higher, and those default settings are crucial in terms of what most patients receive, and if those default settings are set in such a way that you get the most beautiful pictures then it turns out the patients are getting higher radiation doses than they need to support those pictures. So one of the things that the manufacturers are on the ground doing is setting up those protocols with the physicians and there should be guidelines for how those default settings, the settings that most patients experience are setup. So I would say that is one way the manufacturers could help ensure most patients receive the lowest dose possible.

Second, this awareness of the potential harm for radiation is currently getting a lot of attention and the manufacturers actually have a lot of ways to lower dose so the doses for the most typical scans that patients undergo could be reduced by 50 percent without reducing quality at all, and there are lots of ways to make that happen. Dr. McCollough is an expert on how you make those parameters as low-dose as possible but the manufacturers have a lot of expertise around that area as well. They have algorithms that you can apply to existing machinery to lower dose, and I would really push for the manufacturers to make those software products available to everyone who currently owns a CT scan and at a reasonable price so that we can get those dose reduction algorithms out there in active practice. I think on the newer machines that will be sold over the next 5 years, this problem may be addressed to a greater degree but I think we really need to ensure the current scans that are out there are done, and there are ways to lower dose dramatically.

Mr. KLEIN. In regards to radiation therapy and in particular maybe to what happened in Florida, that manufacturer did not have any control over the training of the individual who would have been—who was responsible for determining how the machine was designating the dose rate and that is where the problem was lying. The manufacturer did not have control so that the physicist who was responsible would have demanded, and we drive our manufacturers crazy, to do extra tests to validate that everything was going correctly. However, if the manufacturer had said OK, you are buying this very expensive piece of equipment. It is complex and it is potentially dangerous. We are going to supply an expert physicist to come in from the outside to validate what you are doing. A very simple solution that it would have caught what had happened.

Ms. CASTOR. Thank you very much.

Now, I will yield back so we can get to the next panel.

Mr. PALLONE. Thank you. We are not going to have a second round because we have to go to the next panel but Mr. Whitfield who has been here by himself on the Republican side would like to ask some questions so I am going to let him do so.

Mr. WHITFIELD. I want to thank you for your sympathy and understanding.

When we talk about Federal guidelines for accreditation and reporting of errors and so forth, I want to ask you three physicians,

do we have to be concerned about HIPAA regulations when we get into that area?

Dr. SMITH-BINDMAN. I think one of the problems in easily collecting data is that you don't want to release information about the patient and privacy information that would be concerned. As it turns out for the area that we are talking about, you don't need to release any private patient information. To understand those, you need to know a little bit about that patient such as their age and their sex. None of those are covered by HIPAA, and the dose that they receive, and that is all you need, and none of that data are protected under HIPAA. So I think we use that sometimes as an excuse for not collecting the data but in this particular area for diagnostic imaging, we don't need any of that personal data to understand quality.

Mr. WHITFIELD. And, oh, OK, Dr. Klein.

Mr. KLEIN. There are some databases right now that have a databank of errors that have been reported, the IAEA, and there is also an interesting group, European group called ROSIS, and I can supply that information later. It is all voluntary and everything is anonymous in terms of the patient information and it works very well to learn from that system so I don't think it is an issue really.

Mr. WHITFIELD. OK, I mentioned to Chairman Pallone that if he is going in for radiation he better have his own checklist to look at and then, you know, when we started thinking about that a little bit more and I think that is one of the problems with our medical system today is frequently patients go in and they just make themselves totally compliant to whatever is going on in there. And should we pursue that in areas like this that have such dire consequences that the providers provide the patient or the patient's family with a checklist that they should be focused on as they go through their treatment?

Mr. PALLONE. What we are basically asking is, is there anything you can do proactively as a patient to check what is going on? Now, if you go in, can I ask some questions about what is going on here to make sure that I don't get overexposed?

Ms. MCCOLLOUGH. One of the things we encourage we have a patient information brochure at the check-in desk after you have agreed with your physician that this is an important exam, is just to make sure your physician aware if you have had any exams recently because perhaps the one you are having today isn't necessary. But also we encourage in general the topic of just making sure that the institution knows that they need to right-size the dose, so to speak. Is this exam being tailored for my particular illness or diagnostic question and for my particular body size, as we all come in different shapes and sizes.

Mr. PALLONE. Sure, go ahead. That whistling, I think, is the wind. It is not somebody holding a whistle.

Dr. SMITH-BINDMAN. It is a win situation although for diagnostic imaging if you went in as an informed patient and said to the technologist or the physician, can you tell me what my dose is on this exam, the answer currently would be I don't know. I have received dozens of e-mails and letters and phone calls from patients who are really very concerned about this, and one described his experience

of asking his physician about the radiation dose and he was told by the hospital that he could hire a private physicist if he wanted that information, and that information is in the CT scan albeit it is a little tricky to get out but I think that information belongs in that patient's medical records. So if you as a patient go to the emergency department and they need to give you a medication there is a big sticker that goes on your chart if you have an allergy to a medicine, and we have tried to put checks and balances in place to make sure that if you have an allergy you don't get that medication. I think around the issue of radiation safety, we need to start thinking about that way so when a doctor sees you and orders your test, they know if you have had 15 others of those tests in the last 2 weeks. They might still get that test but that information would be very important so if information is in the medical record, I think doctors could make more informed choices. Certainly, a patient should keep track of everything they have had done and ask the right questions but we need to have a system in place at the other end that there are answers and information that they can get back.

Ms. MCCOLLOUGH. One of—if I could?

Mr. PALLONE. Yes, go ahead, sure.

Ms. MCCOLLOUGH. One of the difficult things about seeing the dose is that the equipment and what the manufacturers can do is say what is this machine putting out. The actual dose to the patient then gets much more complex because it is this interaction of the patient, their body size, with what the machine is putting out. And so the data is very clear as to how the machine is set up and then a physicist can go back and make estimates and models of what that patient got, but unless you went to the extent of almost radiation treatment planning on each and every patient, you really can't tell them what your liver dose or your lung dose without actually having a full CT of their body and then modeling what the scanner gives with them.

I don't think I did a great job answering Ms. Eshoo's question about is this information available, and the number that is available is what the scanner is set up to give for a standard patient. Our technologists look at that rigorously, I mean religiously and that tells them have I set up my exam correctly. Are all my parameters typed in and then at that point the scanner adapts to the patient size. Mammography systems do this, fluoroscopy, radiography because the math that is involved to figuring how much is getting through this size patient or that is something you can't kind of do on the side on a calculator. So most radiographic systems actually have that feedback loop and that is where you can't explicitly say what Mrs. Smith is going to get in her liver because it will take the scan of Mrs. Smith and give the feedback of just how big she is to set the dose.

Mr. PALLONE. All right, thank you very much. So this is very instructive and I know that, you know, several members have said, you know, are we going to do legislation? Do we need a follow-up? I mean we could easily after we have this hearing today decide that we need additional hearings or get back to you and you may get some additional written questions within the next 10 days or so.

So thank you all. We appreciate it and thank you in particular, the Parks and Ms. Lindley, as well. Thank you.

We are going to move to the second panel. All right. It looks like we are very crowded here. I didn't realize that you were going to be rubbing shoulders. So let me start with our second panel and introduce the panelists from my left to right.

First is Dr. Tim Williams who is chair of the board of directors of the American Society for Radiation Oncology. And then we have Dr. Michael Herman who is president of the American Association of Physicists in Medicine. And then we have Sandra Hayden who is vice speaker of the house for the American Society of Radiologic Technologists. And then Dr. Steven Amis who is former chair of the board of chancellors for the American College of Radiology. And then from New Jersey is Kenneth Mizrach who is director of the VA New Jersey Health Care System within the Department of Veterans Affairs. And then we have David Fisher who is executive director of the Medical Imaging Technology Alliance, and finally, John Donahue who is vice chairman of Medicalis, Inc.

Thank you all for being here and I think you were all here before when I said 5 minutes and your full statements become part of the record and then we will have questions. Now, I have to apologize I mean I know when it is a Friday, of course, if the votes are over we don't have as many people participate but, you know, we had originally scheduled this for a day when it snowed, when we had all the snow so when we tried to reschedule it we didn't have a lot of options so that is why we are here on Friday.

And we will start with Dr. Williams.

STATEMENTS OF TIM R. WILLIAMS, M.D., CHAIR, BOARD OF DIRECTORS, AMERICAN SOCIETY FOR RADIATION ONCOLOGY (ASTRO); MICHAEL G. HERMAN, PH.D., PRESIDENT, AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE; SANDRA HAYDEN, B.S., R.T(T), VICE SPEAKER OF THE HOUSE, AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS; E. STEVEN AMIS, JR., M.D., FACR, FORMER CHAIR, BOARD OF CHANCELLORS, AMERICAN COLLEGE OF RADIOLOGY; KENNETH MIZRACH, MHA, DIRECTOR, VA NEW JERSEY HEALTH CARE SYSTEM, DEPARTMENT OF VETERANS AFFAIRS; DAVID N. FISHER, EXECUTIVE DIRECTOR, MEDICAL IMAGING TECHNOLOGY ALLIANCE; AND JOHN J. DONAHUE, VICE-CHAIRMAN, MEDICALIS, INC.

STATEMENT OF TIM R. WILLIAMS

Dr. WILLIAMS. Thank you. Chairman Pallone and Representative Whitfield and members of this distinguished committee, good afternoon and thank you for the opportunity to testify at today's hearing.

I am a practicing, board-certified radiation oncologist and I have been in my location for over 20 years, and I have personally taken care of almost 7,000 cancer patients. I care deeply about the health and safety of my patients.

ASTRO wants patients to have peace of mind when it comes to safety, quality and efficacy of radiation therapy. We are committed to stronger error reporting, enhanced accreditation, better use of

health information technology, patient-centered educational tools and Federal advocacy to help protect patients. I was not involved in any of the tragic situations described by the New York Times but I want to offer my own personal sympathies to those families and particularly the family of Scott Jerome Parks, whose father shared his story with us earlier. His wish was that no one else would go through what he did. We agree. No medical error is acceptable. Cancer patients have enough to worry about.

I have personally witnessed the great benefits of radiation therapy for cancer patients as the medical director of the department of radiation oncology at the Lynn Cancer Institute of Boca Raton Community Hospital. I currently serve as chair of the board of directors of the American Society for Radiation Oncology for whom I am representing here today.

Radiation oncology is an important tool in the fight against cancer, contributing over the past 25 years to steady increases in survival rates for cancer patients. In the mid-1970s, for example, the 5 year survival rate for breast cancer was 75 percent, for prostate cancer it was 69 percent. Today that survival rate has increased to 98 percent for breast cancer and 99 percent for prostate cancer. These are important gains. More are needed.

ASTRO's highest priority is ensuring that patients receive the safest, most effective treatments. A culture of safety and quality control is woven into the fabric of our field with many checks and balances to assure that safe and effective care is delivered to our patients. While ASTRO is alarmed and concerned by the errors described in recent press reports, we do not believe that there are widespread radiation mistakes leading to patient harm across the country. However, the reports do highlight that there is more work to do. Any error, no matter how small, must be reported, understood and utilized as a tool to reduce the potential for future errors. Failing to report known errors is unacceptable.

This moment is an opportunity to further improve our efforts to strengthen the practice of radiation oncology. We have developed a six-point action plan we call target safely. Number one. Work to strengthen error reporting and to create a national database for the reporting of medical errors.

Number two. Advocate for new and expanded Federal initiatives to help protect patients from radiation errors. This includes supporting passage of the CARE Act that requires national standards for radiation treatment team members, supporting increased funding for the Radiological Physics Center at the M.D. Anderson Cancer Center and the quality assurance activities of the Advanced Technology Consortium support a Congressional inquiry into self-referral. ASTRO is concerned that self-referral of radiation therapy services may result in short-changing essential quality control assurance and patient safety protections.

Number three. Work with cancer support organizations to help patients know what to ask their doctors about radiation therapy. Empowered patients who actively engage in their care are important members of our team fighting to beat cancer.

Number four. Enhance the joint ASTRO ACR Radiation Oncology Practice Accreditation program. ASTRO recommends that all radiation oncology practices undergo accreditation.

Number Five. Expand educational training programs to include an intensive focus on quality assurance and safety. ASTRO strongly encourages that all radiation oncologists participate in maintenance of certification.

Number Six. Accelerate our ongoing health information technology interoperability effort. We want device manufacturers to implement standards that allow the transfer of treatment information from one machine to another seamlessly to reduce the chance of a medical error.

ASTRO has been developing and refining many of these programs for years. In today's environment, medical technology and decision-making are increasingly complex. The above plan holds the promise of ensuring patient safety in this challenging atmosphere.

Finally, I would like to demonstrate the benefits of radiation by telling you the story of one of my patients from South Florida. I treated a 50-year-old woman 15 years ago who presented with bilateral breast cancer. At that time, the standard therapy was bilateral mastectomies and the idea of a lumpectomy and radiation for both sides at the same time was considered a very advanced form of therapy. She didn't want both of her breasts removed and we went ahead and proceeded with the lumpectomy on both sides and simultaneous radiation to both breasts. She is now alive 15 years later. I have been following her for the entire time period and she spends time with her family, enjoys a good quality of life and is a true success story for today.

This is what keeps me hopeful and looking for advances in the field. My hope is that patients across the country will recognize these incidents for what they are, isolated acts and that these reports will not dissuade patients who need radiation therapy from receiving needed treatments. We support the committee's review of these issues and we look forward to working with you to further enhance the quality of care patients receive.

Thank you for the opportunity to testify.

[The prepared statement of Dr. Williams follows:]



**Statement of
Tim R. Williams, M.D.,
Chairman of the Board of Directors
On Behalf of the American Society for Radiation Oncology (ASTRO)
Before the Health Subcommittee of the
House Energy and Commerce Committee
February 26, 2010**

Chairman Pallone, Ranking Member Deal, and members of this distinguished committee, good morning and thank you for the opportunity to testify at today's hearing, "Medical Radiation: An Overview of the Issues." I have personally witnessed the great benefits of radiation therapy for cancer patients. I care deeply about my profession and care even more deeply about the health and safety of my patients. I look forward to telling you how radiation therapy works, ASTRO's longstanding efforts to improve quality and patient safety, as well as ASTRO's plans to further enhance patient protections. All patients deserve to feel reassured about their treatment's safety; cancer patients have enough to worry about.

While, I am not personally involved in any of the tragic situations described by the *New York Times* I do want to offer my sympathies to those families and especially to the parents of the courageous Scott Jerome-Parks, who are here today and shared his story. According to the *New York Times* article of January 24th it was his wish that this tragedy be used to make sure no one else goes through what he did. We agree. No medical error is acceptable. I believe my testimony is critical to help Congress and the public understand that radiation therapy is a very safe treatment with a long track record of effectively curing cancer with minimal side effects.

I am the Medical Director of the Department of Radiation Oncology at the Eugene M. and Christine E. Lynn Cancer Institute at Boca Raton Community Hospital, where I've practiced as a board certified radiation oncologist since 1989. We treat about 1,300 patients per year and I have treated more than 6,500 patients in the past 20 years. My medical education was at the Medical College of Georgia, and my residency was at Shands Hospital at the University of Florida. Before moving to the Lynn Cancer Institute, I was an Assistant Professor at the Bowman Gray School of Medicine of Wake Forest University. I serve as the Chairman of the Board of Directors of the American Society for Radiation Oncology (ASTRO), which I am representing today. I have also served as President of the American Registry of Radiologic Technology, President of the Florida Radiological Society, and Councilor to the American College of Radiology from Florida. Additionally, I am the Medical Director of the radiation therapy technology training program for Broward Community College, and a member of the Advisory Committee for Radiation Protection for the State of Florida Department of Health.

As you know, radiation oncology is an important tool in the fight against cancer. Over the last 25 years, the five-year survival rate for cancer patients has increased steadily. Advances in radiation oncology have contributed to saving lives. For example, in the mid-1970s, the five year survival rate for breast cancer was 75%, for prostate cancer it was 69%. Today, the five year survival rate

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has increased to 98% for breast cancer and 99% for prostate cancer. While these are important gains for some of the most common cancers, progress lags for other cancers such as lung, ovarian, and pancreatic cancer where the five-year survival rate remains below 50%.

ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments by providing education and professional guidance to our members. A culture of safety and quality control is woven into the very fabric of our field, and there are many checks and balances, at many levels, to assure that the safest and most effective care is delivered to our patients. We have been a leader in efforts to improve patient safety within our specialty, and protecting our patients from radiation mistakes requires constant vigilance. While ASTRO is alarmed and concerned by the errors described in recent press reports, we do not believe nor is there evidence to support that there are widespread radiation errors leading to patient harm across the country. However, recent reports do highlight to us that there is more work to do to protect our patients. Any error, no matter how small, must be reported, understood and utilized as a tool to further reduce the potential for future errors. Failing to report known errors is unacceptable.

ASTRO's Board of Directors has committed to redouble our efforts with respect to quality and safety so that patients can be reassured about their care. A systemic, 360-degree review of our ongoing patient safety and quality assurance projects was conducted and an action plan emerged, consolidating all of our efforts into a unified six point plan to:

- 1) Work closely with relevant regulatory authorities to create a national database for the reporting of linear accelerator medical errors.
- 2) Significantly enhance the radiation oncology practice accreditation program, and develop additional accreditation modules specifically addressing new technologies, such as Intensity Modulated Radiation Therapy (IMRT), Stereotactic Body Radiation Therapy (SBRT), as well as other radiation treatments.
- 3) Expand our educational training programs to include an intensive focus on quality assurance and safety.
- 4) Work with cancer support organizations to develop tools for cancer patients and their families for use in their discussions with their physicians to help them understand the quality and safety programs at the sites where they are being treated.
- 5) Accelerate an ASTRO-led effort, called Integrating the Healthcare Enterprise – Radiation Oncology (IHE-RO). IHE-RO works to ensure that radiation therapy technologies from different device manufacturers can transfer treatment information seamlessly to reduce the chance of a medical error.
- 6) Advocate for new and expanded federal initiatives to help protect patients from radiation errors, including support for immediate passage of the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy ("CARE") Act to require national standards for radiation therapy treatment team members; additional resources for the National Institutes of Health's investments in this area; and federal examination of the impact of physician self-referral arrangements on the quality of radiation therapy treatments in those clinics.

ASTRO has been developing and refining many of these programs for years, and they have been making a huge difference in the quality of cancer treatment. Now, we are redoubling our

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efforts to ensure that patients receive the safest possible care. We welcome the opportunity to work with this Committee and other stakeholders to gather data and learn about where additional improvements can be made. For instance, we are working with patient support organizations to develop a toolkit for cancer patients and caregivers for use in their discussions with their radiation oncologist to help them understand their quality and safety protocols. This toolkit will include a series of questions to ask their treatment team, such as, “Do you have daily safety checks?” and “What kinds of safeguards do you have to make sure I’m given the right treatment?” It is important to have empowered patients who actively engage in their care.

My hope is that patients across the country will recognize these incidents for what they are – isolated acts – and that these reports will not dissuade patients who need radiation therapy from receiving needed treatments. It’s hard enough to face a cancer diagnosis, and we are concerned that patients may be frightened into not receiving life saving treatments.

ASTRO and Radiation Oncology

Founded in 1958, ASTRO’s mission is to advance the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in the rapidly evolving healthcare environment. Radiation oncologists, radiation oncology nurses, medical physicists, radiation technologists, dosimetrists and biologists comprise ASTRO’s more than 10,000 members, making it the largest radiation oncology organization in the world. These medical professionals, found at hospitals and cancer treatment centers around the globe, make up the radiation therapy treatment teams that are critical in the fight against cancer.

Radiation therapy is a treatment to safely and effectively treat cancer and other diseases. Doctors use radiation therapy to eradicate cancer, to control the growth of the cancer or to relieve symptoms, such as pain. It can be used to treat cancer in almost any part of the body, although breast cancer, lung cancer and prostate cancer typically make up more than half of all patients receiving radiation therapy.

Radiation therapy works by damaging the DNA in cancer cells so that they cannot repair or reproduce. New technology and improved techniques allow radiation oncologists to better target radiation to eliminate cancer cells while protecting healthy cells. As highly trained specialists, radiation oncologists know the various forms of radiation therapy – brachytherapy or external beam radiation – their efficacy in specific cases, and the potential side effects and risks.

Radiation oncology practices, including caring treatment teams of clinical nurses, physicists and technologists, use sophisticated equipment to provide patients with safe, effective care. Radiation oncologists discuss and agree upon treatment options with their patients and their families and plan and deliver that care in conjunction with the patient’s other physicians, as well as non-physician members of the patient’s care team. This team approach assures that the radiation therapy component of a patient’s clinical care fits appropriately in the overall patient treatment plan.

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Training Requirements

Radiation oncologists complete four years of medical school followed by five years of post-graduate training in a radiation oncology residency program. To earn board certification after residency, they must pass three components of a written examination (clinical, radiobiology, and physics) as well as an oral examination. Ninety-eight percent of all practicing radiation oncologists in the United States are board certified. Radiation therapy should only be delivered by physicians who have been specifically trained to deliver this type of treatment.

There are approximately 4,500 board-certified radiation oncologists in the United States, and about half of them must participate in maintenance of certification (MOC) programs to maintain their board-certified status. As you know, MOC programs are designed to evaluate six essential competencies on a continuous basis: medical knowledge; patient care; interpersonal and communication skills; professionalism; practice-based learning and improvement; and system-based practice.

In addition to passing an oral exam every 10 years, the MOC process requires radiation oncologists to attain 200 hours of CME credits (80 percent of which must be related to radiation therapy or oncology), to take eight self assessment modules (SAMs), and to complete three Practice Quality Improvement (PQI) projects. ASTRO currently offers 23 SAMs on a wide range of topics including radiation cancer and biology, thoracic malignancies, gynecologic malignancies, central nervous system tumors, and genitourinary cancers.

ASTRO recently launched a new quality and safety focused self-assessment module on best practices to improve clinical care in radiation oncology. This online education tool provides best practice guidelines for dosimetrists, physicists, therapists, physicians, and nurses. The new module emphasizes the use of peer review, including an analysis of treatment steps that may be prone to human error, documentation of "near misses," development of departmental checklists to catch errors, and engaging the entire radiation oncology treatment team to openly discuss patient safety.

In today's environment, medical technology and decision-making are increasingly complex, and rapid changes in diagnosis and care delivery compound the situation. Initial certification and maintenance of certification offer a strong defense against loss of skills and provide continuous and rigorous quality assurance throughout one's medical career. **ASTRO strongly encourages that all radiation oncologists participate in maintenance of certification and ongoing quality improvement activities.**

In March, ASTRO's journal, which is the leading radiation oncology professional journal, will have a supplement dedicated to practical guidance about recommended radiation dose for 16 organs/disease sites. These articles represent a comprehensive review of the literature and are product of more than 60 physicians and physicists from ASTRO and the AAPM working together. This effort was prompted by a desire to consolidate information about how different radiation doses affect healthy tissue and to identify future research that would help radiation oncologists reduce side effects for patients.

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ASTRO also has led the field in educating radiation oncology team members in advanced technologies and techniques. Specifically, ASTRO began sponsoring a hands-on meeting for radiation oncologists, radiation therapists, physicists and dosimetrists focusing on the treatment team's approach to safe use of IMRT in 2002. We launched another meeting in 2006 focused on the safe use of image-guided radiation therapy (IGRT). Through these programs, ASTRO has educated thousands of professionals about the clinical applications and safe use of these technologies. This year, we have combined the IMRT and IGRT meetings to also include SBRT into a single symposium. These courses provide entire treatment teams with hands on training on the latest technologies. In addition, ASTRO's Annual Scientific Meeting attracts 12,000 medical professionals from around the world who discuss the latest breakthroughs in cancer treatments.

Additionally, ASTRO provides "eContouring" courses, both online and in person. Contouring is the term used to describe how a radiation oncologist outlines the contours of a tumor to best target them for radiation therapy. These sessions are designed to provide crucial clinical education for physicians and provide an opportunity to practice and discuss core treatment issues. Participants have the opportunity to practice contouring and compare their contours to those of world renowned experts in a particular disease site. In addition, participants can take sample cases home with them to continue to practice and further improve their skill.

High quality radiation therapy requires not only highly skilled and well trained physicians, but also medical physicists, dosimetrists, and technologists. **We applaud the leadership of Rep. Barrow, along with seven Members of the Energy and Commerce Committee, for supporting the CARE Act (HR 3652) to require credentialing of these radiation oncology team members. ASTRO supports passage of this important legislation. ASTRO also supports requiring board certification for medical physicists.**

Quality Assurance

Over the last two decades, the sophistication of and technologies available to improve clinical cancer patient care delivered with radiation therapy have advanced dramatically. Modern radiotherapy techniques including 3-D treatment planning, IMRT, stereotactic radiosurgery (SRS), SBRT, IGRT, high-dose-rate (HDR) brachytherapy, and other such sophisticated systems are in wide clinical use. These technologies provide significant new capabilities that can improve our ability to treat and control the patient's cancer while minimizing potential toxicity and side effects. Technology, however, cannot substitute for appropriate medical training and clinical judgment.

The safe use of these new technologies requires the concerted efforts of the entire team involved in the delivery of patient care. This multi-faceted team must continually work together to assure quality throughout all aspects of the treatment planning and delivery processes. A primary focus of this team is to effectively identify risks, develop improved methods for avoidance of errors, and to identify and investigate possible sources of errors.

Error reduction and quality assurance, in particular, has been the subject of major efforts by ASTRO and collaborating organizations including the American Association of Physicists of Medicine (AAPM), American College of Radiology (ACR), and other groups. Collaboration

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between the National Cancer Institute (NCI), ASTRO, ACR, AAPM, and the Food and Drug Administration (FDA) and other organizations, led to a September 2005 roundtable meeting to identify proposals to address improvements in our ability to avoid errors. One of the important outgrowths of this meeting was the creation of the ASTRO quality assurance symposium, "Quality Assurance of Radiation Therapy and the Challenges of Advanced Technologies" held in February 2007.

This symposium directly focused on error prevention, and the quality assurance needs of modern high technology radiotherapy treatment. The symposium participants proposed that our field adopt modern process-oriented and risk-aware failure analysis methods, and systems engineering approaches that have proven successful in other fields. ASTRO and AAPM have launched new initiatives based on this workshop, including presentations and panel discussions, as well as the publication of a special supplement to our professional journal dedicated to papers given at this symposium. Both organizations have groups working to provide quality assurance guidance to the radiation oncology community for IMRT and other high tech procedures. ASTRO currently is working to develop a "Best Practices" paper and on-line course from the results of this symposium to make sure this information is easily accessible and understood by the entire field.

Improving our processes to reduce the risk of error is an ongoing effort. We must continually balance quality assurance checks of equipment and processes that are aimed at avoiding errors with the need for efficient delivery of high quality treatment. New technologies and evolving methods for using existing technologies should be analyzed in detail to develop processes that minimize potential failure, both technological and human. Such analyses require the cooperation of radiation oncologists, medical physicists, dosimetrists, therapists, and other radiation oncology professionals, and related organizations, including the vendor community. Through cooperation and collaboration, these groups must work together to identify possible limitations and failure modes in radiation oncology equipment (hardware and software), in the clinical process for treatment planning and delivery, and in the medical decisions that guide therapy. Systematic quality assurance checks, including peer-review methods, are an important component part of this process. We must continue and accelerate our efforts to improve both technical and medical quality improvement methods.

Reporting Requirements

There is a patchwork of federal and state regulations that applies to the provision of radiation therapy services. While the FDA has authority over the safety of medical devices, the Nuclear Regulatory Commission (NRC) has authority to protect against radiation exposure associated with radioactive materials. States have jurisdiction over patient protection of radiation-producing equipment.

The FDA requires manufacturers of electronic products to report all accidental radiation occurrences arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce. "Accidental radiation occurrence" is defined as a single event or series of events that resulted in injurious or potentially injurious exposure of any person to electronic product radiation (21 CFR 1000.3). In addition, the FDA encourages health professionals and consumers to voluntarily report problems with medical products including

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serious reactions, product quality problems and product use errors. The data collected through voluntary reporting is used to maintain the FDA's safety surveillance of all the products it regulates, and a voluntary report can result in a modification in use or design of the product.

ASTRO sees opportunities for advancing necessary data collection by working with the FDA to reach the goals of the Center for Devices and Radiological Health's FY2010 Strategic Priorities. These goals include putting in place systems and procedures to more efficiently and effectively capture, analyze, and share high-quality information about adverse events (Goal 1.1.3.1), implementing strategies to increase real-time adverse event reporting and establishing pathways for interactive information exchange with healthcare providers (Goal 1.1.3.2), and developing collaborative relationships to promote the establishment of and gain access to registries that provide important information for medical device surveillance (Goal 1.1.3.3). **ASTRO welcomes the opportunity to participate in initiatives underway at the FDA.**

The NRC, which regulates the medical use of radiological materials, requires licensees to report medical events, defined in detail at 10 CFR 35.3045. Medical events include an administration of a wrong radioactive drug, administration by the wrong route, to the wrong individual or delivered by the wrong mode of treatment, or a total dose delivered that differs from the prescribed dose by 20 percent or more or the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

Reporting of medical events or misadministrations involving radiation-producing machines is regulated by each individual state. There is some variability from state-to-state in how a misadministration or a medical event is defined and in the reporting requirements. New York is seen as a leader in its misadministration reporting requirements and data collection. New York regulations [10 NYCRR 16 (Part 16)] define "misadministrations" as a radiopharmaceutical or radiation from a source other than the one ordered, or by route of administration or to a part of the body other than that intended by the ordering physician. Not all events that are defined as misadministrations result in harm to a patient, but all occurrences involve an error or errors in a patient's treatment, and are required to be reported in New York.

To help create a standardized national reporting framework, ASTRO will be working with state regulators through the Conference of Radiation Control Program Directors (CRCPD), a national professional organization of state regulators dedicated to radiation protection. Once standards are developed, we will collaborate on a pilot tracking system for machine-based radiation medical events. Although the overall clinical benefit and safety record for radiation therapy and other radiation procedures is high, ASTRO believes that errors in administration should be tracked for causes and trends to help facilitate the establishment of effective prevention strategies. The pilot would include the development of a definition of reportable events to include radiation therapy using linear accelerators and electronic-brachytherapy technology.

ASTRO supports this Committee's efforts to promote quality measurement and improvement, particularly through the adoption and effective use of health information technology (HIT). ASTRO has devoted significant time and resources to developing clinical guidelines and quality measures for radiation oncology. ASTRO is proud of the high rates of HIT adoption among radiation oncology practices. In addition, ASTRO is leading IHE-RO to develop interoperability

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standards to allow vital clinical information to be passed seamlessly from one manufacturer's radiation oncology system to another system, within and across practices, and made readily available at the point of care. This effort reduces the chances that a medical error can occur. **ASTRO encourages device manufacturers to rapidly implement these interoperability standards as we partner to protect patients.**

Practice Accreditation

In late 2008, ASTRO and ACR entered into an agreement to offer radiation oncology practice accreditation. The accreditation process is designed to promote quality. It includes an on-site survey performed by board certified radiation oncologists and board certified medical physicists. Over the past year, we have been working with our colleagues at ACR to review and strengthen the accreditation program.

In its current format, surveyors review 10 charts of recently treated patients, including de-identified patient records with simulation information and CT planning documentation. The surveyors also collect medical and dosimetry/physics data from the cases selected for review. Each chart is assessed by answering questions on the data collection forms developed by the joint ACR/ASTRO Radiation Oncology Practice Accreditation Committee. The data are used to evaluate information contained in the patient chart, including such items as consent forms, pathology reports, history and physical, physician management during treatment and follow-up, completeness of prescription, simulation, treatment planning and simulation and dosimetry activities. The radiation oncology physicist surveyor is responsible for the design and implementation of the physics quality management program.

Because of the thoroughness of the review, this practice accreditation process is resource intensive. We are exploring creative new ways to increase the pool of volunteer surveyors, such as requiring accredited facilities to provide a volunteer surveyor to review another facility. ASTRO is working with ACR to significantly enhance this practice accreditation program, and to begin the development of additional accreditation modules specifically addressing technologies such as IMRT, SBRT and brachytherapy. **ASTRO is recommending that all radiation oncology practices undergo practice accreditation.**

NCI Investments

ASTRO has long advocated for increased funding for the National Cancer Institute (NCI), and we appreciate the efforts of this Committee to strengthen the NCI in its battle to defeat this dreaded disease. It is hard to find a family in this nation that has not been touched by cancer and we need all the resources possible to alleviate the suffering it causes. Indeed, one of the many reasons that ASTRO supports increased funding for NCI is the important work done by the one-of-a-kind Radiological Physics Center at the M.D. Anderson Cancer Center in Houston. ASTRO strongly supports the important work of the RPC to ensure that institutions participating in clinical trials deliver prescribed radiation doses that are clinically comparable and consistent. We believe that RPC's auditing and monitoring tools have led to improved radiation dosimetry. RPC is an NCI grantee with a budget of approximately \$3.5 million per year, \$2.5 million of which comes from NCI and the rest from fees levied on participating institutions. Unfortunately, RPC's funding has decreased over the past decade.

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ASTRO is aware of and troubled by 2008 RPC data showing that approximately 30 percent of participants failed to accurately irradiate head and neck phantoms, which simulate human patients. While RPC uses more stringent standards for determining accuracy than regulatory agencies, quibbling over the data misses the point: there is room for improvement. Prior to and since the release of RPC's data, numerous institutions have worked with the RPC to identify and resolve problems. RPC also has called problems to the attention of manufacturers, who have used the information to upgrade their equipment and software. We greatly appreciate the efforts of the RPC to shed light on shortcomings, develop quality assurance protocols, and help educate the radiation oncology community to resolve quality problems. We are confident that participating institutions will continue to improve their performance in future RPC analysis. ASTRO also has incorporated information and tools from the RPC to develop enhanced quality assurance programs to educate its membership.

ASTRO also supports the mission of the Advanced Technology Consortium (ATC) at Washington University's School of Medicine in St. Louis. The ATC capitalizes on the existing infrastructure of national quality assurance programs. It facilitates and supports NCI sponsored advanced technology clinical trials, particularly those requiring digital data submission. This effort includes radiation therapy quality assurance, image and radiation therapy digital data management, and clinical research and developmental efforts.

ASTRO asks Congress to support increased funding to expand the capabilities of the RPC and ATC to deal with increasingly complex treatment technologies and processes as well as to further analyze already existing data to ascertain their clinical significance.

Physician Self-Referral

ASTRO has expressed concern to Congress and the Administration that financial incentives and the self-referral of radiation therapy services in the Medicare program may be leading to patients not being fully informed on the full range of treatment options and potentially to the overutilization of health care services. ASTRO also is concerned about anecdotal information indicating that when self-referral is in place, those business arrangements often can cut corners on important quality assurance and patient safety essentials like having robust staffing and qualified medical physicists on-site. We believe Congress should request a study to examine the quality of radiation therapy delivered to patients when self-referral is involved.

Conclusion

Finally, I would like to illustrate the benefits of radiation therapy by telling you the story of one of my patients. I treated a 50 year old woman in 1995 for bilateral breast cancer. A breast cancer diagnosis is always scary, and in the mid-1990s, we were in the process of making the discoveries that have led to the current overall 98 percent five year survival rate for breast cancer patients. At that time, her surgeon recommended bilateral mastectomies, but she opted for bilateral wide excisions followed by radiation. Both breasts were treated at the same time, and we used what was then considered a new, advanced technology called 3D conformal radiation. She is now 15 years out from treatment, lives a full life, spends time with family and friends, and still has both her breasts. Together with the treatment team, we successfully treated her tumors while preserving her quality of life. This is what keeps me hopeful and looking forward to advances in the field.

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In sum, ASTRO wants patients to have peace of mind when it comes to safety, quality and efficacy of radiation therapy. We are committed to stronger error reporting, more training, enhanced accreditation, better use of health information technology, patient-centered educational tools and federal advocacy to help protect patients. ASTRO shares the Committee's concerns about the health and safety of all patients and recognizes the importance of maintaining access to high quality cancer treatment. **We support the Committee's review of these issues. We look forward to working with you on policies that could be implemented to further enhance the quality of care patients receive.**

Thank you again for the opportunity to testify.

Mr. PALLONE. Thank you, Dr. Williams.
Dr. Herman.

STATEMENT OF MICHAEL G. HERMAN

Mr. HERMAN. Chairman Pallone and distinguished members, good afternoon. Thank you for the opportunity to testify.

My name is Michael Herman and I am president of the American Association of Physicists and Medicine. Medical physicists are responsible for accuracy, quality and safety of the radiation-producing technology and diagnostic imaging and radiation therapy. Although rare, medical errors can be devastating. We all wish that no one ever made a mistake but errors still can and do occur due to a combination of unlikely events occurring sequentially or simultaneously, many times under unusual circumstances that involve complex systems.

The use of medical radiation occurs in radiation oncology and in radiology practices with millions of people receiving that radiation annually to their benefit. Each patient procedure is a complex, multi-system process which combines technology and human actions. To make the process work requires coordination and participation of a team of humans, physicians, medical physicists, dosimetrists, radiation therapists, radiation technologists. All focus on the treatment of each patient.

One of AAPM's primary goals is to identify and implement improvements and patient safety for the medical use of radiation. We do this through our association's activities and in cooperation with other societies and regulatory and government bodies. Some of these include the development of procedures and guidelines, producing detailed scientific educational and practical reports, guidance to regulatory and accrediting bodies, oversight of quality assurance and calibration processes, facilitating medical information system communication and providing education on medical errors.

AAPM believes that the position of qualified medical physicists should be recognized nationally for anyone practicing clinical medical physics. A qualified medical physicist is an individual who has completed a unique combination of graduate education, rigorous clinical training and board certification in medical physics. All of these efforts mentioned move us toward more effective patient care and in achieving the absolute minimum error rate, however, some challenges remain.

There is no consistent national recognition of qualified medical physicists. Medical physicists are licensed in only four States in this country and regulated at widely varying levels in the other States. The reports and guidelines that AAPM and others publish have only the force and effect of professional and scientific guidelines. There are no consensus national staffing guidelines for qualified medical physics services nor are there consistent standards established for accrediting practices that utilize medical physics services.

So what can we do? Well, much effort and progress is being made to improve quality of care and increase patient safety but we can and must do more. Together medical radiation team members, professional associations, manufacturers and government must strive for nationally consistent recognition of the qualified medical physi-

cist and equivalent competency for all medical radiation team members by passing H.R. 3652, the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Act of 2009, and specifically requiring that all medical physicists involved in medical imaging and radiation therapy be included in this bill. Provide consistent procedure-specific consensus minimum standards for national practice guidance in radiation oncology and medical imaging that recognize qualified individuals for specific responsibilities. Define communication of the team. Establish minimum staffing levels and receive timely review and amendment. Establish a rigorous minimum standard for all bodies at accredit clinical medical radiation practices based on the previously mentioned staff list national guidance that includes additional accredit requirements for highly-specialized procedures. Link CMS reimbursement to rigorous practice accreditation for all medical imaging and radiation therapy practices. Create a national data collection system to learn from actual and potential adverse events in the medical use of radiation that allows complete and consistent reporting by medical staff, manufacturers and others. Improve the review effectiveness of product quality in the equipment clearance process.

In summary, we believe that patient safety and the use of medical radiation will be increased through consistent education and certification of medical team members, whose qualifications are recognized nationally, and who follow consensus practice guidelines that meet established national accrediting standards. We have been working together for years on many of these issues. We must do more and we need some help. Together we will continue to make the use of medical radiation safer and more effective for the people that need it.

Thank you for the opportunity to speak to you today.
[The prepared statement of Mr. Herman follows:]



American Association of Physicists in Medicine

**Statement of Michael G. Herman, Ph.D., FAAPM, FACMP
On Behalf of the American Association of Physicists in Medicine (AAPM)
Before the Subcommittee on Health of the House
Committee on Energy and Commerce
February 26, 2010**

Chairman Pallone, Ranking member Deal and members of this distinguished committee, good morning and thank you for the opportunity to testify today on Medical Radiation: an Overview of the Issues.

It is my pleasure to be here representing the American Association of Physicists in Medicine, known generally as the AAPM. AAPM is a scientific and professional organization, founded in 1958, composed of nearly 7000 scientists whose clinical practice is dedicated to ensuring accuracy, safety and quality in the use of radiation in medical procedures such as medical imaging and radiation therapy. We are generally known as medical physicists and are uniquely positioned across medical specialties due to our responsibility to connect the physician to the patient through the use of radiation producing technology in both diagnosing and treating people. The responsibility of the medical physicist is to assure that the radiation prescribed in imaging and radiation therapy is delivered accurately and safely. As such, our members are deeply saddened by the tragic events recently reported.

The use of medical radiation occurs in radiology and radiation oncology practices with millions of people receiving that radiation to their benefit annually. Patients and the public may see the results of medical radiation, but few understand how it is done. Each patient procedure is a complex multi-system process, in which each system involves a combination of technology and human actions. To make the process work requires the coordination and participation of teams of human beings: physicians, medical physicists, dosimetrists, radiation therapists, radiologic technologists, information system engineers, linear accelerator and other vendor related engineers, nursing and support staff – all of these individuals and all of their effort must be focused on the treatment of each patient.

Although rare, medical errors can be devastating. We all wish that no one ever made a mistake, even more so, no event that could injure another person. But errors still can and do occur due to a combination of unlikely events occurring sequentially or simultaneously, many times under unusual circumstances that involve the complex systems in the delivery of this type of medical care.

One of the primary goals of the AAPM is the identification and implementation of improvements in patient safety for the medical use of radiation in imaging and radiation therapy. We do this through our association's activities and in cooperation with other societies such as the American Society for Radiation Oncology (ASTRO) and the American College of Radiology (ACR). I would like to mention some of the steps we have taken, and continue to take to increase safety for our patients.

- The AAPM participates in the development of procedures and guidelines for the safe, efficacious implementation and utilization of existing, new and advanced technologies. This

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includes developing cooperative technical standards with the ACR and performing new technology/procedure assessment with ASTRO.

- The AAPM is a founding member of the Image Gently Alliance for radiation safety in pediatric imaging and of the new Image Wisely Campaign for safer imaging in adults.
- The AAPM produces many detailed scientific, educational and practical reports for technology and procedures for medical imaging and radiation therapy. These reports include specific processes for radiation dose measurement and calibration, quality assurance and peer review. These reports are presented in educational forums at national and regional meetings and are also publicly available.
- The AAPM has initiated a comprehensive review of existing reports and recommendations to identify areas for improvement.
- The AAPM provides medical physics guidance to the Intersociety Accrediting Commission (IAC) and cooperates with the ACR accrediting program. We intend to reach out to the newly designated accrediting body for advanced imaging modalities, the Joint Commission.
- The AAPM initiated (over 40 years ago) and provides oversight of the Radiological Physics Center in Houston, Texas, which is federally funded to provide medical physics and quality review support to the National Cancer Institute (NCI) and national clinical trials groups.
- The AAPM accredits national dosimetry calibration laboratories, which provide accurate calibration of field instruments used by medical physicists to determine clinical dose levels.
- The AAPM has been a leader and partner in guiding and facilitating improved system connectivity and communication in the medical information environment, specifically as it relates to accurate information transfer during procedures that use medical radiation.
- The AAPM provides education on medical errors, error analysis and reduction and responds rapidly to needs in the area of technical quality and safety. For example:
 - The special Quality Assurance meeting held in 2007, together with ASTRO and NCI;
 - A Computed Tomography (CT) Dose Summit is occurring in April, 2010 to address CT dose protocol consistency; and
 - A Safety in Radiation Therapy meeting to include treatment team members, manufacturers, government agencies, and patient interest groups is planned for June 2010.

In addition to these activities, AAPM has devoted a substantial part of its energy to the creation and recognition of a position known as Qualified Medical Physicist, or QMP. These physicists have a unique combination of education in the principles of physics, radiobiology, human anatomy, physiology and oncology through a graduate degree, as well as clinical training in the applications of radiation physics to medicine, such as the technologies of medical imaging and treatment delivery, radiation dose planning and measurement, as well as safety analysis and quality control methods. Following this, an individual demonstrates competence in his/her discipline by obtaining board certification (currently offered for ionizing radiation imaging and radiation therapy through the

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American Board of Radiology). Certification is a rigorous, multi-year process that requires considerable supervised clinical experience as well as passage of written and oral examinations. The AAPM recognizes a Qualified Medical Physicist for the purpose of providing clinical medical physics services, as an individual who is board-certified in the appropriate medical subfield and has documented continuing education.

All of the efforts mentioned are aimed at providing safer, more accurate and more effective patient procedures using medical radiation and we will continue to work toward achieving the absolute minimum error rate. However, there are some challenges we face in trying to meet these goals:

- While the AAPM has a clear definition of a Qualified Medical Physicist, there is no consistent national recognition of this credential. Medical physicists are licensed in 4 states (TX, NY, FL, and HI) and regulated at widely varying levels in the other 46 states.
- The reports that AAPM (and others) publish have only the force and effect of professional and scientific guidelines.
- There are also no consistent national staffing guidelines for medical physics services nor are there consistent standards established for accrediting practices that utilize medical physics services.

Specific Areas of Focus to Improve Patient Safety in the Medical Use of Radiation

The following are specific areas where much effort has been placed and progress is being made, yet we can and must do more to improve the quality of care and increase patient safety. Together we all (medical radiation team members, professional associations, manufacturers and government) must:

1. Provide robust, consistent, and financially-stable education, training and clinical experience for the Qualified Medical Physicist in clinical practice. To achieve this, we must:
 - continue strong support for the AAPM 2012/2014 initiative, which will meet the goal of requiring every candidate who applies to take the American Board of Radiology medical physics exams to receive structured didactic medical physics education and complete an accredited clinical residency prior to completing the certification exam beginning in 2014 and
 - obtain recognition for medical physics residency programs for Centers for Medicare & Medicaid (CMS) reimbursement equivalent to that of physician residencies.
2. Strive for nationally consistent recognition of the Qualified Medical Physicist and equivalent competency for all medical radiation team members by:
 - passing H.R. 3652, "The Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009"(CARE Act) and specifically requiring that all medical physicists involved in medical imaging and radiation therapy be included in the bill and
 - facilitating consistent implementation of the CARE Act nationally.
3. Provide national practice guidance in radiation oncology and medical imaging based on consensus and consistent minimum quality standards. Standards must:

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- recognize qualified individuals; specifically the Qualified Medical Physicist,
 - establish minimum staffing levels,
 - require that Qualified Medical Physicists be involved in the supervision of the processes that determine image quality and patient dose/exposure,
 - define procedure-specific guidance, including explicit process communication within and beyond the medical team, and
 - undergo periodic review with timely amendment or replacement when necessary.
4. Establish a rigorous minimum standard for accrediting clinical practices that specifically includes the oversight of dose and quality assurance for medical imaging and radiation therapy technology. This standard should require that:
 - sites have work performed per national practice guidance by qualified individuals with appropriate staffing levels,
 - additional accreditation requirements are established for highly specialized procedures, and
 - practice reviews be performed by qualified individuals.
 5. Link Centers for Medicare & Medicaid (CMS) reimbursement to rigorous practice accreditation for all medical imaging and radiation therapy practices to insure steps one through four above are followed.
 6. Create a national data collection system to learn from actual and potential adverse events in the medical use of radiation. The system must:
 - allow reporting by medical staff and manufacturers and others in a complete and consistent manner,
 - be searchable to identify patterns, risks and corrective actions and to provide education, and
 - require a partnership between all involved (federal and state government, manufacturers, users, patient advocates).
 7. Improve the effectiveness of product clinical quality, application and integration review in the regulatory equipment clearance process by partnering with the U.S. Food and Drug Administration (FDA), the International Electrotechnical Commission, (IEC) and manufacturers.

In summary, the AAPM believes that patient safety in the use of medical radiation will be increased through: consistent education and certification of medical team members, whose qualifications are recognized nationally, and who follow consensus practice guidelines that meet established national accrediting standards. We must also learn from our mistakes by collecting and evaluating them at the national level. AAPM has been working directly and in cooperation with other stakeholders for years on some of these issues and we are saddened that some people are injured during what should be beneficial procedures. We believe that more effort on all seven areas of focus, by all of us, working cooperatively, will continue to make the use of medical radiation safer and more effective for the people that need it.

Thank you for the opportunity to talk to you about medical physics and our efforts toward patient safety in the medical use of radiation.

Mr. PALLONE. Thank you, Dr. Herman.
Ms. Hayden.

STATEMENT OF SANDRA HAYDEN

Ms. HAYDEN. Mr. Chairman.

Mr. PALLONE. It sounds like it is working. Go ahead.

Ms. HAYDEN. Mr. Chairman and members of the committee, my name is Sandra Hayden and I am a radiation therapist at M.D. Anderson Cancer Center in Houston. I also serve on the board of the American Society of Radiologic Technologists and it is in that role that I address you today.

On behalf of the ASRT's 134,000 members, thank you for the opportunity to contribute to this dialogue on the quality of radiation therapy and other medical procedures that use radiation. Radiation therapy is the cornerstone of cancer management programs worldwide. It can contain, control and cure cancer however radiation therapy must be precise to be effective. Accuracy is equally important during medical imaging exams that diagnose cancer. X-ray exams, CT scans and other imaging tests use radiation and radiation comes with some risk. Errors, although rare, can cause devastating side effects.

The ASRT believes the best way to ensure quality and safety of medical radiation procedures is to establish national educational and certification standards for technical personnel who perform them. CT scanners, gamma cameras and linear accelerators are some of the most complex medical equipment in the world however this technology is ineffective in the wrong hands. That is because the quality of any medical radiation procedure is directly linked to the scale and competence of the person performing it. Individuals must have extensive education and training to perform the exam correctly. Patient safety is in the hands of these individuals yet they remain largely unregulated.

Radiographers are not licensed in eight States. Radiation therapists such as myself are not regulated in 17 States, including the District of Columbia. Medical physicists have no oversight in 31 States and no State regulates medical dosimetrists. Even in States with some type of regulation, the rules are sometimes so weak they offer patients little protection. In some States hairdressers are better regulated than people who perform medical radiation procedures.

Unqualified personnel are a danger to patients. An underexposed x-ray can't reveal a malignant tumor. An inaccurate radiation therapy treatment can't stop its spread. Even worse, when medical radiation is used improperly it can harm the very patients it was meant to help as you have heard from earlier.

The solution is the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy bill. The CARE bill introduced by Representative Barrow as H.R. 3652 and pending before Congress since 2000 uses a three-tiered approach to improving quality and safety.

First, individuals who perform medical imaging and radiation therapy would be required to graduate from a specialized educational program. Second, they would be required to pass a na-

tional certification exam and third, they would be required to maintain competency by obtaining continuing education.

Only qualified personnel should be allowed to perform medical imaging or radiation therapy. The CARE bill will ensure a minimum level of education, knowledge and skill for those who are responsible for medical radiation procedures. For patient safety, the ASRT encourages Congress to pass the CARE bill.

The ASRT also calls for consistent and mandatory methods of reporting medical radiation errors. Mistakes must be reported and investigated so others may learn from them. By learning how errors occur, we can implement safeguards to prevent them.

Currently, States and Federal oversight of radiation errors is inconsistent. Regulatory bodies do not share information. Even worse, some States do not require that errors be documented at all. The ASRT calls for mandatory reporting of medical radiation errors and also for a consistent system of data collection and tracking.

A model to consider is the FDA's MedWatch program which takes a systemic approach. A reporting system such as MedWatch would build a knowledge based on patient safety and help reduce errors.

Thanks to medical imaging and radiation therapy millions of Americans are cancer survivors. The vast majority of medical radiation procedures are administered safely and successfully however any mistake is unacceptable. ASRT's recommendation will lead to safer care and will help more patients win the battle against cancer.

Thank you again for inviting me to speak on this important issue.

[The prepared statement of Ms. Hayden follows:]



Ensuring Safe, Accurate Medical Radiation Procedures
Statement by the American Society of Radiologic Technologists

Submitted to the House Energy and Commerce Committee, Subcommittee on Health

“Medical Radiation: An Overview of the Issues”
February 26, 2010

Testimony delivered by Sandra Hayden, B.S., R.T.(T)
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Mr. Chairman and members of the Committee, my name is Sandra Hayden, and I am a radiation therapist at MD Anderson Cancer Center in Houston. I also serve on the board of the American Society of Radiologic Technologists, and it is in that role that I address you today. On behalf of ASRT’s 134,000 members, thank you for the opportunity to contribute to this dialogue on the quality of radiation therapy and other medical procedures that use radiation.

As recently as the 1950s, few cancer patients had any hope of long-term survival. Diagnosis of the disease was difficult, and treatment options were limited both in type and effectiveness. Today, thanks to better diagnostic capabilities and aggressive treatment, many types of cancer are being cured and more people are surviving the disease than ever before.

In particular, external beam radiation therapy, which delivers a high dose of cancer-killing radiation directly to a tumor site, has dramatically improved the chances of survival for

many cancer patients. Radiation therapy is now the cornerstone of cancer management programs worldwide. Nearly two-thirds of Americans diagnosed with cancer – more than 1 million patients a year – undergo radiation therapy as part of their treatment. Administered accurately, radiation therapy can ease pain, control the spread of cancer and, in many cases, cure patients of disease. However, radiation therapy must be precise in order to be effective.

Accuracy is equally important during the medical imaging exams that physicians rely upon to diagnose cancer. Medical imaging is used during virtually every stage of a patient's cancer management program, from initial detection to staging the tumor's size and shape to following up to ensure that treatment has been effective. The x-ray exams, CT scans and other imaging tests performed on cancer patients use radiation, and radiation comes with some risk. Errors, although rare, can cause devastating side effects.

The ASRT believes the best way to ensure the quality and safety of medical radiation procedures is to establish national educational and certification standards for technical personnel who perform them.

CT scanners, gamma cameras and linear accelerators are some of the most complex medical equipment in the world. However, this technology is ineffective in the wrong hands. That's because the quality of any medical radiation procedure is directly linked to the skill and competence of the person performing it. Individuals must have extensive education and training to perform the exam or treatment correctly.

The effective detection and treatment of cancer demands precision, reliability, consistency and a level of teamwork that few other professions can match. The medical team responsible for detecting and treating cancer includes the patient's primary care physician, a radiologic technologist who performs the imaging exams, a radiologist who interprets those

images and makes a diagnosis, a radiation oncologist who determines the best course of treatment, a medical physicist who designs the treatment protocol, a medical dosimetrist who calculates the proper radiation dosage, and a radiation therapist who delivers the prescribed amount of radiation and provides direct patient care.

Patient safety is in the hands of these individuals, yet many members of the cancer management team are largely unregulated in terms of education, experience and competence. Radiographers are not licensed or regulated in eight states; radiation therapists are not regulated in 17 states; medical physicists have no oversight in 31 states; and no state licenses medical dosimetrists. Even in states with some type of regulation, the rules are sometimes so weak that they offer patients little protection. In some states, hairdressers are better regulated than people who perform medical radiation procedures.

Unqualified personnel are a danger to patients. An underexposed x-ray can't reveal a malignant tumor, and an inaccurate radiation therapy treatment can't stop its spread. Even worse, when medical radiation is used improperly it can harm the very patients it was meant to help.

Cancer patients should not have to wonder whether the person performing their CT scan or planning their radiation therapy treatment is competent.

The solution is the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy bill.

The CARE bill, introduced in the House of Representatives by Rep. John Barrow in September 2009 as H.R. 3652, asks the federal government to establish minimum educational and credentialing standards for technical personnel who perform medical imaging examinations and who plan or deliver radiation therapy treatments. Each state then would be responsible for regulating personnel according to those standards.

The CARE bill uses a three-tiered approach to improving quality and safety. First, individuals who perform medical imaging or radiation therapy would be required to graduate from a specialized educational program. Second, they would be required to pass a national certification exam. And third, they would be required to maintain competency by obtaining continuing education. Together, these three criteria will help ensure that personnel have the skills to perform their duties competently and free of error.

Only qualified personnel should be allowed to perform medical imaging and radiation therapy. When a CT scan has to be repeated because of improper positioning or poor technique, the patient receives double the radiation dose. Taking a CT scan or delivering radiation therapy involves much more than just pushing a button. Patients could be injured or even killed if this equipment is not used properly. The CARE bill will ensure a minimum level of education, knowledge and skill for those who are responsible for medical radiation procedures.

In addition, the CARE bill will reduce health care costs. Repeated medical imaging examinations cost the U.S. health care system millions of dollars annually in needless medical bills, and the federal government pays for many of those mistakes. If we can reduce the number of repeated x-ray, fluoroscopy and sonography examinations by just 1 percent, the ASRT conservatively estimates Medicare could save \$50 million to \$70 million over five years.

More importantly, reducing errors in medical imaging will mean that cancer patients will receive an earlier diagnosis, when the disease is most treatable and before it has spread to other parts of the body. To improve the quality of patient care, the ASRT's 134,000 members encourage Congress to pass the CARE bill.

The ASRT is not alone in its support for the CARE bill. The bill is backed by the Alliance for Quality Medical Imaging and Radiation Therapy, a coalition of 25 organizations that

represent more than 500,000 health care professionals. In addition, the bill has received support from patient advocacy groups, including the American Cancer Society.

The safety, quality and cost of medical imaging procedures affects us all. Only competent personnel should be allowed to perform these procedures. The CARE bill will ensure a minimum level of education and skill for those who are responsible for medical imaging and radiation therapy. By requiring personnel to meet national standards, the CARE bill would help ensure that patients receive the best care possible, provided by the most qualified caregivers possible.

As an additional step to improve the quality and safety of medical radiation procedures, the ASRT calls for the establishment of consistent and mandatory methods of reporting medical radiation errors.

Errors that occur during medical radiation procedures, while rare, must be reported and investigated so that others may learn from them. Quality-oriented medical facilities and health care professionals continually strive to learn from their mistakes to ensure that they are not repeated. By investigating how, why and where medical errors occur, providers can implement safeguards to prevent them.

Currently, state and federal oversight of radiation therapy errors is uncoordinated and inconsistent. A variety of agencies and regulatory bodies are involved, and they often do not share information with one another. Reporting of medical radiation errors is voluntary in some states, and other states do not require that errors be documented at all. As a result, important information is lost that could be used to establish patterns of concern or identify critical issues.

The ASRT calls for mandatory, public reporting of errors that occur during medical radiation procedures, and also for a consistent system of data collection and tracking.

A reporting model to consider is the FDA's MedWatch program, which takes a systemic approach to the reporting of adverse medical events. This is the approach recommended by the Agency for Healthcare Research and Quality. Establishment of a reporting system such as MedWatch would represent an unprecedented opportunity to build the knowledge base on patient safety and reduce errors.

Thanks to medical imaging and radiation therapy, millions of Americans are cancer survivors. The vast majority of medical radiation procedures are administered safely and successfully. However, radiation comes with risk, and more can and should be done to improve the safety of patients. The recommendations offered by ASRT will lead to safer patient care and will help more patients win the battle against cancer.

Thank you again for inviting me to speak on this important issue.

Mr. PALLONE. Thank you, Ms. Hayden.
Dr. Amis.

STATEMENT OF E. STEVEN AMIS, JR.

Dr. AMIS. Chairman Pallone, Congressman Whitfield and distinguished members of the subcommittee, thank you for the opportunity to speak today.

I am Dr. Steven Amis, Professor and Chair of Radiology, The Albert Einstein College of Medicine in Montefiore Medical Center in New York. I am a past president of the American College of Radiology and I am testifying today in my capacity as chair of ACR's blue ribbon panel on radiation dose in medicine.

The ACR which represents more than 36,000 radiologists, radiation oncologists, nuclear medicine physicians and medical physicists is committed to ensuring appropriate use of radiation in medicine. One message I must highlight today is that the proper use of radiation in medicine whether diagnostic or therapeutic saves lives and improves the quality of care for millions of patients each year.

Please consider the following. Advances in medical imaging have rendered exploratory surgery virtually obsolete. Interventional radiologic procedures often replace more invasive surgical options resulting in approved outcomes and reduced hospital stays, and over one million patients each year are cured or experience relief of pain due to treatment of their tumors with radiation therapy.

Still as has been known for the past 100 years, recent media reports remind us that the medical use of radiation is not without risk. We can and must do a better job of preventing errors.

The ACR has long been involved with numerous radiation-related quality improvement initiatives. These include development of guidelines to ensure that patients get the right exam or treatment performed in the right way. Creation of registries and other tools to help physicians compare their outcomes with those of their peers, and education of radiologists, fellow physicians and the public about the risks and benefits of both diagnostic and therapeutic radiation. Of particular note, ACR strongly supports Image Gently, an educational initiative conceived by pediatric radiologists to promote safe imaging of children.

To help prevent further adverse radiation-related events, ACR asks that Congress seriously consider the following recommendation and we are not pulling any punches. A formal accreditation process must be mandatory for all diagnostic imaging service and radiation therapy practices. In this process hospitals and free-standing facilities should be held to the same standards as patients have a right to safe and high-quality care regardless of the setting in which they receive it. Such a process should be robust and focus on considerations unique to imaging and radiation therapy such as image quality, dose monitoring, phantom testing, equipment calibration and maintenance, and the qualifications of all involved personnel.

As a corollary, since CT scans are a growing cause of radiation exposure in the United States, a CT dose registry should be required as a component of accreditation for CT practices. This would help ensure ongoing compliance with accreditation baseline.

ACR has been working with industry to develop such a registry but a Congressional mandate would facilitate this process. Congress has already recognized the importance of accreditation. MQSA requires accreditation of mammography practices and has helped save tens of thousands of lives. A similar approach is seen in MIPPA. It has already been described, which requires accreditation of non-hospital-based imaging practices. Both MQSA and MIPPA offer important lessons on how to design an optimal accreditation process.

Further, it is essential that the accrediting bodies have a proven track record in imaging and radiation therapy accreditation. The ACR is the nation's oldest and most recognized medical imaging and radiation therapy accrediting body and is the only nationwide FDA approved accrediting body for MQSA. ACR accreditation designed to be educational in nature is an efficient process of both self-assessment by the practice being reviewed and independent, external audit by physicians and medical physicists who are recognized experts in the specific type of practice being evaluated.

We recognize there is a desirable middle ground between an accreditation process that is overly burdensome and one that lacks the substance to ensure quality and safety. We stand ready to work with members of this committee to find the right balance.

Thank you again for the opportunity to testify and for holding this hearing on such an important topic.

[The prepared statement of Dr. Amis follows:]


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Statement of E. Stephen Amis, Jr., M.D., FACR
Former Chair, Board of Chancellors, American College of Radiology
To the
House Energy and Commerce Health Subcommittee's
Hearing on
"Medical Radiation: An Overview of the Issues"

February 26, 2010

Chairman Pallone and Distinguished Members of the Subcommittee:

On behalf of the American College of Radiology (ACR)—a professional organization representing more than 36,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—I appreciate the opportunity to discuss the importance of quality and safety in the medical use of radiation. The ACR is deeply committed to ensuring the appropriate use of medical radiation in all modalities and clinical settings, and we believe this can best be achieved through robust mandatory accreditation of medical imaging and radiation therapy. In addition to expressing our support for mandatory accreditation, ACR would also like to share with the Health Subcommittee some of ACR's efforts to improve medical imaging and radiation therapy services through our quality and safety programs, education and public awareness campaigns, and related projects.

First and foremost, it should be emphasized that medical imaging and radiation therapy procedures irrefutably save lives and improve patient care. Advances in medical imaging over the past few decades have rendered exploratory surgery virtually obsolete. Disease processes can be discovered and characterized earlier, and treatments can be monitored more readily to allow for optimal patient care. Image-guided medical procedures have replaced more invasive surgical options for many patients while improving outcomes and reducing hospitalization and recovery times. Furthermore, clinical trials and experience have demonstrated the benefits of radiation therapy in curing cancer, extending life, and alleviating pain and suffering for over one million patients each year.

However, the series of New York Times articles that gave rise to this hearing was a heart-wrenching reminder that the benefits received from medical radiation are not without risk. As a profession, we can and must do a better job of preventing such errors – not only to ensure all patients get the best quality of care we can provide, but also to maintain the confidence of the public who rely on our care. The ACR believes that the best way to address this is through expansion of existing federally mandated medical imaging accreditation requirements to encompass all clinical settings and radiation therapy modalities, enacting new minimum standards for technologists such as H.R. 3652, the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009 or CARE Act, using experienced accrediting bodies to run the program and requiring a CT dose index registry.

Accreditation

The ACR is the nation's oldest and most recognized medical imaging and radiation oncology accrediting body with a long history of developing and administering accreditation programs that assess the quality of imaging facilities. Designed to be educational in nature, ACR accreditation is an efficient process of both self-assessment and independent external expert audit, based on the ACR practice guidelines and technical

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standards, which assesses the qualifications of personnel, policies and procedures, equipment specifications, quality assurance (QA) activities, patient safety, and ultimately the quality of patient care.

ACR accreditation began in 1987, with the then-voluntary mammography and radiation oncology accreditation programs. Due to ACR's success with the voluntary mammography program, Congress passed the Mammography Quality Standards Act (MQSA) in 1992 to mandate accreditation of all mammography facilities. In 1994, the ACR became the only national accrediting body for mammography to be approved by the Food and Drug Administration (FDA) under MQSA.

Mandatory mammography accreditation has been credited with saving tens of thousands of women's lives and vastly improving the quality of patient care since the implementation of MQSA. Much of the success of MQSA can be attributed to the fact that FDA did not attempt to recreate the wheel when establishing the standards it would adopt. Instead it built upon standards and processes that were already being successfully implemented on a voluntary basis within the profession. Further, rather than relegating the quality review to federal employees who may not have had practical experience in the field, MQSA relies upon accrediting bodies, named and reviewed by FDA, to serve these functions.¹

In addition to the mammography and the now joint ACR and American Society of Therapeutic Radiology and Oncology (ASTRO) radiation oncology programs, the College developed accreditation programs for ultrasound (1995), stereotactic breast biopsy (1996), magnetic resonance imaging (1996), breast ultrasound (1998), nuclear medicine (1999), computed tomography (2002) and radiography/fluoroscopy (2002). Like the radiation oncology program, these other accreditation programs were not mandatory. However, Congress adopted accreditation requirements as a requisite to Centers for Medicare and Medicare Services (CMS) payment for advanced diagnostic imaging services as part of the Medicare Improvements for Patients and Providers Act (MIPPA) in 2008. The MIPPA requirements represented a paradigm shift in which Congress made the decision to tie payment to quality and safety in medical imaging.

During implementation of the MIPPA provisions, CMS recognized the ACR, the Intersocietal Accreditation Commission (IAC), and the Joint Commission in January 2010 as deemed accrediting organizations. However, not all accreditation programs are robust enough to sufficiently improve quality and safety. Accreditation can only be successful if the accrediting bodies can clearly demonstrate their experience, expertise, and a track record in evaluating quality and phantom review in the overseen modalities. These elements are the foundation of any valid accreditation program and were specifically included in the medical imaging provisions contained in MIPPA.

While previously voluntary accreditation programs for certain medical imaging modalities will become mandatory in ambulatory settings in 2012 due to MIPPA, radiation oncology accreditation remains voluntary and participation is not as extensive as is clearly needed. This is made evident by the fact that the radiation oncology accreditation program is utilized by less than 10% of radiation therapy practices in the country. Congress must step in and mandate accreditation for radiation therapy per the lessons learned by MQSA and MIPPA.

ACR Appropriateness Criteria

In addition to its respected accreditation programs, the ACR offers other important quality and safety resources to the radiology and referring physician communities, not the least of which being the ACR Appropriateness Criteria (AC). The ACR Task Force on Appropriateness Criteria was created in 1993 to

¹ Destouet JM, Bassett LW, Yaffe MJ, Butler PF, Wilcox PA. The ACR's Mammography Accreditation Program: ten years of experience since MQSA. *J Am Coll Radiol.* 2005 Jul;2(7):585-94.

develop nationally accepted, scientifically-based guidelines to assist referring physicians in making appropriate imaging decisions for given patient clinical conditions. Currently, the ACR AC are the most comprehensive, evidence based guidelines for diagnostic imaging selection, radiation therapy protocols, and image-guided interventional procedures. There are 167 topics with over 800 variants as of the September 2009 iteration. ACR has also worked with software vendors to include ACR AC in computerized radiology order entry systems to address appropriateness of imaging orders by referring physicians.² By using these guidelines in making decisions regarding radiologic imaging and treatment, physicians enhance quality of care and contribute to the most efficacious use of radiology services.³

With regard to radiation dose, the ACR AC is guided by the principle that the overall risk of cancer induction from a diagnostic imaging procedure involving ionizing radiation is small, but it is not zero. Therefore, ACR AC recognizes the importance of minimizing patient radiation exposure and avoiding the ordering of unnecessary examinations. ACR AC advises referring physicians who are planning to order an imaging exam for their patient to consider the patient's previous imaging examinations. Above all, any exposure that accompanies an imaging examination should be justified based on the benefit to the patient.

In 2008, Congress recognized the potential for better patient care and reducing imaging utilization by including a demonstration project for AC in MIPPA. Future data from this demonstration project may indicate the value of expanding the use of AC to all physicians throughout the country, which the ACR strongly supports. Currently, despite the benefits in terms of quality, safety, and cost-effectiveness, the voluntary utilization of AC by referring physicians who order medical imaging studies is relatively low.⁴

"Image Gently" and "Image Wisely" Awareness Campaigns

ACR helped launch the Image Gently campaign in January 2008 as a founding member of The Alliance for Radiation Safety in Pediatric Imaging—a coalition of 41 organizations dedicated to raising awareness and promoting education about radiation protection for children undergoing medical imaging examinations. The Image Gently campaign is an effort to help ensure that medical protocols for the imaging of children keep pace with advancing technology. The goal of the campaign is to educate radiologic technologists, medical physicists, radiologists, pediatricians and parents about radiation dose used during the more than 4 million pediatric computed tomography (CT) examinations performed on children in the U.S. each year. The program has been recently expanded to include pediatric interventional radiology procedures as well.

The Image Gently website includes protocols that can be used to optimize pediatric technique used during CT imaging of children based on weight. The campaign emphasizes the need to differentiate these methods for children compared to adults. To date, 3,973 providers have taken the pledge on the Web site to "image gently" when performing pediatric imaging exams.

Due to the success of the campaign for pediatric CT, ACR and the Radiological Society of North America (RSNA) began the Image Wisely campaign to expand the principles and educational resources of the Image Gently campaign to CT imaging of adult patients. Image Wisely's partners have grown to include the American Association of Physicists in Medicine (AAPM) and the American Society of Radiological

² Siström CS, Dang PA, Weilburg JB, Dreyer KJ, Rosenthal DI, and Thrall JH. Effect of Computerized Order Entry with Integrated Decision Support on the Growth of Outpatient Procedure Volumes: Seven-year Time Series Analysis. *Radiol* 251: 147-155; 2009.

³ Hadley JL, Agola J, Wong P. Potential impact of the American College of Radiology appropriateness criteria on CT for trauma. *AJR Am J Roentgenol*. 2006 Apr;186(4):937-42.

⁴ Bautista AB, Burgos A, Nickel BJ, Yoon JJ, Tilara AA, Amorosa JK; American College of Radiology Appropriateness. Do clinicians use the American College of Radiology Appropriateness criteria in the management of their patients? *AJR Am J Roentgenol*. 2009 Jun;192(6):1581-5.

Technologists (ASRT). When rolled out in 2010, the Image Wisely Campaign will feature educational resources for radiologists, medical physicists, and technologists, and will eventually work on increasing awareness in the referring physician and patient communities.

ACR National Radiology Data Registry: Dose Index Registry

Another pertinent ACR program is the Dose Index Registry (DIR), which will collect and provide feedback on radiation dose estimate information from various modalities. A pilot program focusing on CT that allows participants to compare average volume CT dose index (CTDI_{vol}) and the dose length product (DLP) values across facilities is currently in progress, and there are plans to expand the pilot in 2010.

DIR is part of the ACR's larger National Radiology Data Registry (NRDR) program, which is a data warehouse for the DIR, General Radiology Improvement Database (GRID), National Mammography Database (NMD), CT Colonography (CTC), National Oncologic Positron Emission Tomography (NOPT), and IV Contrast Extravasation (ICE) data registries. The primary purpose of NRDR is to aid facilities with their quality improvement programs and efforts to improve patient care by comparing facility data to that of their region and the nation. Participating facilities may choose to share data with any or all registries as appropriate for their practice, and ultimately use NRDR to compare their own performance to that of other participants.

Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009

The ACR strongly supports H.R. 3652, the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009 or CARE Act, which would require personnel performing the technical components of medical imaging and radiation therapy to meet federal education and credentialing standards in order to participate in federal health programs. The ACR encourages passage of the CARE Act in concert with mandated accreditation, dose index registry requirement, and the other aforementioned programs.

Conclusion

Although the use of radiation in medicine saves lives and improves patient care, the recent New York Times articles remind us that the use of medical radiation has certain risks. The ACR recognizes that even the most strenuous accreditation programs will never eliminate all medical errors in the respective services being accredited; however, the success of MQSA is proof that mandatory accreditation helps to significantly reduce these risks and ultimately improve quality.

The ACR believes Congress should expand the current MIPPA accreditation requirements for advanced imaging to include radiation therapy. In addition, the accreditation mandate should apply to all facilities, including hospital settings. Furthermore, the accrediting of these imaging and radiation therapy procedures should only be conducted by those accrediting bodies with experience and expertise in the area for which they are accrediting. Lastly, a required dose index registry would be a critical new component that could measure ongoing performance of the accreditation baseline. Such a dose registry index may have helped identify many of the problems covered in media reports far sooner. ACR has been working with industry to develop such a registry but a congressional mandate would aid this process.

As always, the College is ready to assist the Subcommittee and Congress in accomplishing these goals so that we can improve the treatment, safety and quality of care for our patients.

Mr. PALLONE. Thank you, Doctor.
Mr. Mizrach.

STATEMENT OF KENNETH MIZRACH

Mr. MIZRACH. Good afternoon, Mr. Chairman. Thank you for the opportunity to share the radiation oncology experience at the VA New Jersey Health Care System.

I will describe for you our 3-year journey that includes how we identify the problem and the quality of care for radiation oncology patients, how we responded and how we rebuilt our program to make sure that these circumstances would not happen again. Transparency was our constant focus throughout this process and guided our decisions to ensure that we acted in the best interest of our patients, and as soon as we determine that specific patients did not receive the quality of care they deserved, we disclosed this information to 53 patients and their families consistent with the Veterans Health Care Administration policy.

Of the 53 patients, we determined that two patients were harmed. We informed the other 51 patients that they experienced errors that created a risk for them for the future. We are following these patients for any subsequent signs of injury resulting from the identity of any of these errors.

Prior to December of 2006, the East Orange campus of the VA New Jersey Health Care System radiation oncology program was accredited by a nationally recognized, external, reviewing agency. Our patients were satisfied. Staff members had no complaints and all indications suggested our program was delivering quality care.

In December of 2006, we first heard that two radiation therapy contract technicians unexpectedly were no longer reporting to work at our facility. When we inquired as to why this happened, we learned that they had raised concerns about the quality of care being providing resulting in a conflict with the supervisory staff.

We immediately initiated a review that included a series of increasingly detailed investigations of the quality of care in radiation oncology. The first review by a quality manager validated that the concern raised by the technicians were credible. In response, we made the decision to close the program down until a thorough review was complete and we were certain our program provided safe, quality care for our veterans.

Patients in the need of radiation therapy have received care through fee-basis arrangements with local accredited facilities in their communities. Subsequent reviews by external VHA teams of experts and final comprehensive review by the American College of Radiology confirmed there were deficits in our programs. These included issues of staff qualifications and communication, implementation of new technology without adequate education and training, gaps in procedures for managing patients and the lack of a robust, quality assurance program.

These findings became the framework for rebuilding our radiation oncology program. We needed to be sure we would deliver the highest standard of care possible and implement corrective actions to rectify all deficits identified by the ACR.

During the course of the investigation, the clinical staff who had been working in our programs resigned. At the same time, the con-

tract for radiation therapy technicians and for contract physicists expired. We then made the decision that it would not be renewed.

We began by improving our program by hiring new staff members including a nationally respected, experience and board-certified chief of radiation oncology. We also hired properly trained and credentialed physicists, a dosimetrist and radiation therapy technicians.

As radiation therapy is complex and rapidly changing, we established a program of continuous education for all staff and a major component of this initial and ongoing training of new technology and equipment. We next established policies and procedures to guide patients' care and instituted a comprehensive quality management program.

Such a program includes meeting the standards established by the American College of Radiology. This entails identifying quality control for every step of radiation therapy including the dose and technique prescribed, the energy the machine delivers, the dose of radiation the patient receives and how the patient responds to the therapy. We are continuing the routine tests of our machines simulating patient encounters, checking dose calculations, tracking patient outcomes and instituting routine quality reviews of care including peer review.

A culture of openness is fundamental to patient safety. This means an environment where all staff members are considered an equal part of the health care team. To this end, we established multi-disciplinary team meetings prior to, during and after treatment to review all aspects of care. We encourage our staff members at all times to raise questions of concern about that care being provided. The most important lesson we learned through this process was that staff members must be able to communicate openly to feel comfortable about raising issues and to feel confident that leadership will respond to their concerns.

Thank you again for the opportunity to share my experience. I am now available for questions at a later time.

[The prepared statement of Mr. Mizrach follows:]

STATEMENT OF
KENNETH H. MIZRACH, MPH
DIRECTOR, VA NEW JERSEY HEALTH CARE SYSTEM
VETERANS HEALTH ADMINISTRATION
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES
FEBRUARY 26, 2010

Good Morning, Mr. Chairman. Thank you for the opportunity to share the Radiation Oncology experience at VA New Jersey Health Care System. I will describe for you our 3 year journey that includes how we identified a problem in the quality of care for radiation oncology patients, how we responded, and how we rebuilt our program to make sure that these circumstances would not happen again. Transparency was our constant focus throughout this process, and guided our decisions to ensure we acted in the best interest of our patients. As soon as we determined that specific patients did not receive the quality of care they deserved, we disclosed this information to 53 patients and their families consistent with Veterans Health Administration (VHA) policy. Of the 53 patients, we determined that two patients were harmed. We informed the other 51 patients that they experienced errors that created a risk for future harm. We are following these patients for any subsequent signs of injury resulting from the errors identified.

Prior to December 2006, the East Orange Campus of the VA New Jersey Health Care System's radiation oncology program was accredited by a nationally recognized external reviewing agency. Our patients were satisfied, staff members had no complaints, and all indications suggested our program was delivering quality care. In December 2006, we first heard that two radiation therapy contract technicians unexpectedly were no longer reporting to work at our facility. When we inquired as to why this happened, we learned that they had raised concerns about the quality of care being provided, resulting in conflict with supervisory staff. We immediately initiated a review that included a series of increasingly detailed investigations of the quality of care in radiation oncology. The first review by our quality manager validated that the concerns raised by the technicians were credible. In response, we made the decision to close the program until a thorough review was complete and we were certain our program provided safe, quality care for our Veterans. Patients in need of radiation therapy have received care through fee basis arrangements with local accredited facilities in their communities.

Subsequent reviews by external VHA teams of experts and a final comprehensive review by the American College of Radiology (ACR) confirmed there were deficits in our programs. These included issues with staff qualifications and communication, implementation of new technology without adequate education and training, gaps in procedures for managing patients, and the lack of a robust quality assurance program.

These findings became the framework for rebuilding our radiation oncology program; we needed to be sure we would deliver the highest standard of care possible and implement corrective actions to rectify all deficits identified by the ACR.

During the course of investigation, the clinical staff who had been working in our program resigned. At the same time the contract for radiation therapy technicians and for contract physicists expired; we then made a decision that it would not be renewed. We began improving our program by hiring all new staff members, including a nationally respected, experienced and board certified Chief of Radiation Oncology. We also hired properly trained and credentialed physicists, a dosimetrist, and radiation therapy technicians. As radiation therapy is complex and rapidly changing, we established a program of continuous education for all staff, and a major component of this is initial and ongoing training of new technology and equipment.

We next established policies and procedures to guide patient care and instituted a comprehensive quality management program. Such a program includes meeting the standards established by the American College of Radiology. This entails identifying quality controls for every step of radiation therapy including the dose and technique prescribed, the energy the machine delivers, the dose of radiation the patient receives and how the patient responds to the therapy. We are conducting routine tests of our machines, simulating patient encounters, checking dose calculations, tracking patient outcomes, and instituting routine quality reviews of care, including peer review.

A culture of openness is fundamental to patient safety. This means an environment where all staff members are considered an equal part of the health care team. To this end, we established multi-disciplinary team meetings prior to, during, and after treatment to review all aspects of care. We encourage our staff members at all times to raise questions or concerns about the care being provided. The most important lesson we learned through this process was that staff members must be able to communicate openly, to feel comfortable about raising issues, and to feel confident that leadership will respond to their concerns.

Thank you again for the opportunity to share my experience with you. I am now available to answer your questions.

Mr. PALLONE. Thank you, Mr. Mizrach. Thank you for being here too, today. I appreciate it.

Mr. Fisher.

STATEMENT OF DAVID N. FISHER

Mr. FISHER. Mr. Chairman, Congressman Whitfield, Congresswoman Castor, thank you for the opportunity to be here today.

I serve as the executive director of the Medical Imaging and Technology Alliance, the leading association representing the manufacturers, innovators and developers of medical imaging and radiation therapy systems. We are here today because of a tragic situation and as an industry we are committed to doing our part to prevent such things from occurring in the future.

At the outset, it is important to note that computed tomography, CT, and radiation therapy, RT, are very different modalities used for different purposes. CT is a diagnostic tool that utilizes ionizing radiation to create detailed images of internal tissues. Radiation therapy or RT on the other hand, is a therapeutic tool that utilizes a focused beam of radiation to kill cancer cells. Due to their distinct purposes, the amount of radiation associated with these modalities differs by orders of magnitude.

These two modalities have revolutionized health care delivery. The New England Journal of Medicine recently called medical imaging one of the top health care innovations ever. Likewise, radiation therapy offers highly personalized, non-invasive and cost effective care for up to 60 percent of all diagnosed cancer patients in the U.S.

MITA has a long history of working with its members, physicians, physicists, technologists, regulatory bodies and other stakeholders to track and reduce medical radiation. Our members continue to introduce new products in system innovations that reduce radiation dose for many procedures while continually improving image quality. New technologies like weight and age-based protocols, automatic exposure control, software improvements and improved interfaces with operators all enable dose reduction.

MITA is also working collaboratively with other stakeholders on issues related to medical radiation and the use of radiation in the equipment. For example, in November of last year, MITA convened a meeting including physicians, physicists, industry and Food and Drug Administration official to discuss ways to prevent future medical errors that involve ionizing radiation. MITA is also cosponsoring an upcoming CT dose summit and is also considering a radiation therapy summit to work with the AAPM on a radiation therapy summit to further the education of providers, physicists and others on the new technologies, dose reduction technologies in particular our companies manufacture.

As part of the access to medical imaging coalition, MITA helps to develop appropriateness criteria for advanced medical imaging included in the Medicare Improvements for Patients and Providers Act or MIPPA. More recently, MITA announced its support for the President's proposal in the fiscal year 2011 budget to develop a National Dose Registry. We also welcome the FDA's recent actions regarding radiation dose and support many of the policies proposed in their initiative to reduce unnecessary radiation exposure for

medical imaging. MITA intends to participate fully with FDA as they work to implement dose reduction policies and MITA has also recently made two announcements in the area of radiation dose that may be of interest to this committee.

Yesterday, MITA announced a new dose check initiative in which CT manufacturers committed to do three things. First, a new radiation dose alert feature which is designed to provide a clear indication that the settings for the CT exam will result in a dose higher than a predetermined reference dose for routine scans. Second, manufacturers are committed to including a dose warning feature to prevent CT scanning at higher, potentially dangerous radiation levels. This feature is designed to prevent hazardous levels of radiation that could lead to injuries. This feature can also be configured by hospitals or imaging facilities to prevent scans at these higher radiation levels. Third, manufacturers will also standardize dose reporting to help better understand dose levels and facilitate the development of the National Dose Registry proposed by the President.

Several weeks ago MITA also announced a dose reduction plan including the development of radiation dose reference levels to assist clinicians to understand the relative amount of radiation associated with the scan. Expansion of the appropriateness criteria mentioned earlier to ensure that patients receive the right test at the right time, the development of training standards for hospitals and free-standing imaging facilities that purchase imaging equipment that involve the use of radiation and radiation therapy equipment, efforts to develop safety checklists to reduce medical errors and to incorporate those new standards into our training offerings. Efforts to ensure standardize reporting across stakeholders in a manner that is transparent for patients, their families and physicians. An examination of whether the MIPPA accreditation policy should be expanded to include additional facilities where radiation therapy medical devices are in use, and the establishment of minimum standards for radiologic technologists who perform diagnostic medical imaging exams and deliver radiation therapy treatments.

In each of these cases, MITA and our member companies stand ready to work with professional organizations, regulatory bodies, individual clinicians and other stakeholders on these features. Lastly, MITA continues to work with all of our members whose companies manufacture products that ionizing radiation to develop new ways to reduce dose and reduce medical errors, and I am hopeful we will continue to make strides in this area. As we look to the future of health care in this country, we cannot see our way to better outcomes and lower costs without the lens that medical imaging provides. The medical technologies MITA member companies research, develop and manufacture are the future of delivering better health outcomes at lower costs.

Thank you for this opportunity today. As the legislation process proceeds, MITA looks forward to continuing to work with Congress and the Administration to ensure appropriate use of and access to medical imaging and radiation therapy.

[The prepared statement of Mr. Fisher follows:]

Testimony of David Fisher
Executive Director, Medical Imaging and Technology Alliance
Energy and Commerce Health Subcommittee
February 26, 2010

Mr. Chairman and Ranking Member, I would like to thank you for your invitation to testify today. It is an honor to be here to speak about the important issue of medical radiation.

I am here today as the Executive Director of the Medical Imaging & Technology Alliance (MITA), the leading association representing the manufacturers, innovators and developers of medical imaging and radiation therapy systems. Our more than 50 member companies comprise more than 90 percent of the market for X-ray imaging, computed tomography (CT), radiation therapy, diagnostic ultrasound, nuclear medicine imaging, magnetic resonance (MR), and medical imaging informatics equipment.

MITA is a division of the National Electrical Manufacturers Association (NEMA), a long-established standards-development organization. NEMA standards include widely accepted guidelines for medical imaging equipment that utilizes radiation, as well as other voluntary guidelines that establish commonly accepted methods of design, production, and testing.

I'd like to begin by stating unequivocally that MITA and its member companies believe that any medical error is one too many and that we want to work with the Committee, relevant agencies, providers and patients to reduce the number of medical errors to as low a number as possible.

Value of Radiation Therapy and Medical Imaging

Radiation therapy and medical imaging such as computer tomography (CT) are two complementary but distinct aspects of patient care involving medical radiation that have revolutionized health care delivery in America.

Not only has the *New England Journal of Medicine* proclaimed medical imaging one of the top "developments that changed the face of clinical medicine" during the last millennium, along with anesthesia and antibiotics, but physicians on the front lines of patient care reinforce that belief each and every day. As one example, in the Dartmouth-Stanford Survey of Medical Innovations, leading general internists ranked MRI and CT technology as the most valuable medical innovations in the last 30 years.

As we continue to innovate, we were heartened to hear President Obama in his State of the Union address specifically reference "treatment that kills cancer cells but leaves healthy ones untouched," as an example of what is possible through innovation. Thanks to the leading-edge research and development of our member companies, the President's vision is not far from reality. To this end, it is critical that health care policies continue to facilitate, not restrict, industry innovation.

With an estimated 1.4 million Americans diagnosed with cancer in 2008 alone, and malignancies claiming over half a million lives, access to radiation therapy is essential for ensuring high quality cancer care. Radiation therapy has become a standard of care for treating many types of cancer. Evolved far beyond the large field, one size fits all therapies of the past, modern radiation therapy

offers highly personalized, tailored, non-invasive and cost-effective care for up to 60 percent of all diagnosed cancer patients in the U.S. That translates to approximately 850,000 Americans each year who are able to attack their cancer.

Both medical imaging and radiation therapy are integral to established medical guidelines. These guidelines reflect clinical recommendations developed by specialty physician groups on how best to diagnose and treat specific medical conditions. They are based upon proven best practices, widely accepted standards and scientific evidence. Some examples include the following:

- Guidelines by the American Heart Association and the American College of Cardiology recommend use of CT and other imaging technologies to diagnose peripheral arterial disease.ⁱ
- Guidelines developed by the American Cancer Society, the American Medical Association, the American College of Radiology, the National Cancer Institute and the American College of Obstetrics and Gynecology recommend regular mammograms for woman and regular MR imaging for women in specified high-risk categories.
- Guidelines by the National Comprehensive Cancer Network on the most appropriate treatments for various disease sites.
- Guidelines developed by the American Association of Physicists in Medicine that define necessary quality assurance measures for intensity modulated radiation therapy to ensure accurate and safe treatment for cancer patients.ⁱⁱ
- Guidelines by the National Cancer Institute define standards of care for screening and testing of specific cancers.ⁱⁱⁱ

Our technologies are not only fundamental to standards of care, but they also help patients avoid or limit more invasive procedures, and return to their families, lives, and work more quickly. Indeed, it is because of these advanced technologies that the term “exploratory surgery” is all but obsolete.

For most of us, our own experiences bear this out. We have either benefited personally from or know someone whose life was saved or improved by these technologies. The mother whose MRI of the breast will detect cancer in time to avoid radical surgery. The father who's chest CT tells his doctor that the blockage is worse than anticipated and immediate action is needed. The aunt, uncle, grandparent, and cousin whose Intensity Modulated Radiation Therapy (IMRT) saved their life.

Beyond the anecdotes and what common sense dictates, we also know that the value of medical imaging and radiation therapy is demonstrated empirically.

From receiving a CT scan instead of a cardiac catheterization or detecting a polyp before it is cancerous, or receiving a course of radiotherapy that allows a patient to keep his daily schedule of work and home commitments rather than endure invasive surgery, peer-reviewed research confirms that these medical technologies not only improve health outcomes and save lives, but also reduce health care costs and drive down spending.

Just to give you a brief snapshot into the power of medical imaging and the curative effects of radiation therapy, consider these research findings:

- Increased regular mammography screenings have resulted in a 24 percent decrease in the death rate from breast cancer from 1990 - 2004. If detected early, the five-year survival rate for breast cancer exceeds 95 percent.^{iv}

- A recent study in the *Lancet* found that in women who recently underwent mastectomy, the five-year risk of local breast cancer recurrence was only 6 percent for women who also received radiation therapy, compared to 23 percent for those without. Radiation therapy provides a similar advantage in women who undergo breast conserving surgeries or lumpectomies.
- For all cancers, physicians have reported that PET scanning allowed them to avoid additional tests or procedures 77 percent of the time. Moreover, in over 36 percent of cases, PET scanning resulted in a physician's decision to alter their patient's course of treatment.^v
- Used together, external beam radiation therapy and Brachy therapy (where a radiation source or "seed" is placed inside the area requiring treatment) have demonstrated five-year PSA-based cure rates of 96-100 percent for low risk patients and 69-97 percent for those at high or very high risk.^{vi}
- A recent study showed that after treatment with a boosted dose of radiotherapy following a course of external beam radiotherapy, patients with locally advanced nasal carcinoma had excellent outcomes. Five years later, 98 percent of patients were free from local relapse, 83 percent were free from nodal relapse, and overall survival was 69 percent.^{vii}
- Coronary Computed Tomographic Angiography (CCTA) rules out coronary artery disease with over 90 percent accuracy, saving patients from unnecessary surgery or un-needed trips to the cath lab.^{viii}
- Increased utilization of advanced medical imaging, such as CT and MRI, between 1991 and 2004 improved life expectancy by 0.62 to 0.71 years. This effect was greater than the increases in mortality caused by obesity over the same timeframe.^{ix}

Simply put: innovative medical imaging and radiation therapy technologies turn patients into survivors.

Beyond the life-saving impact of medical imaging, researchers have also found that it saves money in the long-run.

For example, every \$1 spent on inpatient imaging correlates to approximately \$3 in total savings,^x and according to researchers at Harvard Medical School, every \$385 spent on imaging decreases a patient's hospital stay by one day, saving approximately \$3,000 per patient.^{xi xii}

Other, disease specific studies have found that increased imaging could save up to \$1.2 billion annually in the treatment of stroke patients,^{xiii} and since 1998, CT scans have been found to significantly reduce the negative appendectomy rate and the number of unnecessary hospital admissions, saving \$447 per patient.^{xiv}

In short, as we look to the future of health care in this country, we cannot see our way to better outcomes and lower costs without the lens that medical imaging and minimally invasive radiotherapy provides. The medical technologies MITA's member companies research, develop and manufacture are the future of delivering better health outcomes at lower costs.

Proactively Ensuring the Safe and Effective Use of Medical Radiation

Each year, millions of treatments and imaging sessions involving the use of medial radiation are completed without error because of the efforts of clinicians, manufacturers, and regulators to adhere to extensive current procedures and standards. Efforts to promote safety over the last several decades have reduced the incidence of errors and misadministration to their lowest levels.

For example, during the design process an extensive analysis is done to evaluate the potential for malfunctions and errors that might affect patient or operator safety and the quality of treatments. For each possible error, remedies are designed, which may include fail-safe interlocks, operator warnings, safe operating procedures, etc. All of these remedies are then tested and documented as part of the verification and validation of the product before it can be released for use.

The utmost care is taken so that imaging devices that use radiation and radiation therapy devices are installed appropriately, calibrated, and ready for clinical use. Additional quality and safety checks are performed frequently, in accordance with guidelines established by the American Association of Physicists in Medicine (AAPM), the Radiological Society of North America (RSNA), and the equipment manufacturer.

When errors or malfunctions that affect patient safety are reported to manufacturers, they inform the Food and Drug Administration (FDA), investigate the cause to determine what actions should be taken to reduce or eliminate the possibility of harm in the future.

Industry Innovations Reduce Radiation Dose and Improve Safety

The imaging industry supports and is committed to the ALARA principle, which stands for "as low as reasonably achievable." This is a universally adhered to principle of radiation dose management and optimization incorporated into all imaging procedures and technologies and is mandated by nearly all regulatory bodies and licensing agencies, including the Nuclear Regulatory Commission.^{xv} This foundational industry consensus principle to minimize and optimize radiation exposure demonstrates the commitment of all involved parties to patient dose concerns, both in the short and long term.^{xvi}

CT Imaging

In addition to working with medical professionals and federal agencies on efforts to reduce dose during imaging procedures, our members have introduced new products and system innovations during the past 20 years that have reduced radiation dose for many procedures by up to 75 percent, while maintaining, and even improving image quality, enhancing the ability of physicians to diagnose and treat disease.

CT innovations have been especially prevalent with significant advancements that have effectively "built-in" dose reduction into the equipment. For example:

- Weight-based, age-based and other CT scan protocols have been developed by luminary imaging institutions around the world and manufacturers incorporate these protocols into new equipment to help users achieve optimum diagnostic results. These protocols are designed as a starting point for doctors and imaging facilities to provide appropriate diagnostic information while minimizing radiation, and are particularly effective in optimizing dose for children and infants.
- Automatic exposure control (AEC) alters the amount of radiation dose used when scanning different parts of the body. For example, more tube current is needed to maintain image quality during a CT scan in a large or dense area of the body as compared to smaller areas. AEC protocols automatically adjust the current up or down within prescribed bounds as needed, without relying on the imaging technologist. Studies of AEC procedures have shown radiation dose reductions between 20 and 60 percent.^{xvii}

- Beam collimation limits dose delivery to coincide with the detector area of interest and scanning field of view, thereby minimizing the photons that do not contribute to the image.
- Beam filtration reduces low energy photons likely to be absorbed by the patient (and not contribute to image formation). They can also shape the beam to optimize it for patient size.
- Adaptive software filtration is governed by noise management software to selectively reduce noise in uniform areas of an image while preserving edges. This enables a lower dose to be utilized while preserving image quality.
- Dose display. CT imaging equipment provides access to dose data, generally by displaying the data on the console, in consistently defined parameters, prior to scanning. This allows the operator to better understand the dose implications of protocol choices and how any change to the protocol will affect dose.
- ECG tube current control for CT cardiac examinations. The advent of cardiac imaging resulted in an additional modulation method based on cardiac cycle as opposed to body location. The primary focus of cardiac dose modulation is to ensure that dose is only delivered during the resting phase of the ECG cycle to reduce the effects of image degrading motion and motion associated artifacts.

It is important however to keep in mind that dose reduction depends not only on equipment, but also on the use of the equipment and the physician determination of the appropriate dose levels for each individual patient. MITA and our members work closely with the physicians and radiologic technologists who use this equipment. We value their feedback and cooperation in developing initial and ongoing training related to these products.

Radiation Therapy: Safe, Targeted, Effective

In the case of diagnostic imaging technologies that use radiation to create images, we are seeking to reduce dose. On the other hand, radiotherapy requires a high amount of narrowly targeted radiation aimed at the cancerous cells to cure and to control the cancer. Radiation therapy provides safe and effective treatment for an increasingly wide range of cancers. By delivering a targeted high dose of radiation directly to cancerous tissue, radiation therapy causes the malignant cells to either stop growing or to die, while simultaneously minimizing radiation exposure to surrounding healthy tissue.

During the past several years, researchers have developed highly targeted and customizable radiation planning and delivery tools. These advances in radiation oncology are translating directly into better clinical outcomes, as well as greater safety and convenience for patients such as fewer treatment-related side effects and complications, and shorter and more convenient courses of therapy. Generally a non-invasive, radiation therapy is often performed in the outpatient setting, which minimizes disruption of daily activities for many of the estimated 643,000 cancer patients who receive radiation treatments each year.

Based on evidence from a large and ever-expanding body of scientific and medical literature, radiation therapy has become integral to medical guidelines and best practices as a standard of care for many types of cancer including breast, prostate, lung, head and neck, rectal, and central nervous system tumors. In some cases, radiation treatments are used instead of surgery. Alternatively, they may be used pre-operatively to shrink a tumor and provide for less invasive, safer and more effective surgery or used post-operatively to prevent disease progression or spread after surgery.

In addition, guidelines for clinical use of radiation therapy have been developed by a number of different national organizations and medical specialty groups, such as the National Comprehensive

Cancer Network and the American Society of Clinical Oncology (a professional organization representing over 25,000 oncologists and others who provide care for cancer patients).

Radiation therapy is prescribed by radiation oncologists to treat cancerous tumors or other diseases that respond to therapeutic radiation. The modern radiotherapy process is a series of steps designed to deliver the radiation oncologist's prescription of radiation dose. This process makes use of a variety of hardware and software equipment to diagnose, prescribe, plan, verify and deliver the patient's treatment.

Systems typically used in the radiotherapy process include:

- Diagnostic systems, which allow the radiation oncologist to locate the disease within the patient and define the shape of the targeted tumor;
- Treatment planning systems, which allow the physician, medical dosimetrist, and medical physicist to calculate the amount of dose that different potential treatments will deliver to the patient's tumor and surrounding tissue and even vary the plan as the patient's treatment needs change;
- Treatment information management systems, which contain the patient's medical chart, including the prescription, schedule of treatments, specific instructions for the treatment machine, a record of treatments completed, patient images, billing data, and other information that is used by clinicians to assure quality and safety;
- Quality assurance systems, with which the medical physicist verifies the calibration of the treatment machine and the accuracy of a patient's specific treatment plan prior to and during the course of the patient's treatment; and
- The treatment machine, which consists of a treatment couch used by the radiation therapist to precisely position the patient prior to treatment using a variety of imaging and positioning sub-systems, and the radiation delivery system itself, which is used by the Radiation Therapist to control, deliver, and monitor the radiation beam(s) in accordance with the approved prescription and the patient's chart.

Hardware and software systems used in the radiotherapy process have multiple safety features designed to assure safe and effective completion of the treatment prescribed by the radiation oncologist. Treatment management systems typically do continuous consistency and integrity checks of the data that controls the radiation dose that will be delivered to the patient. They verify that all pieces of critical data are present before the treatment will be allowed to proceed. The system also checks that the particular patient's treatment plan matches with the requirements and capabilities of the treatment machine and prevents the start of treatment if there is a discrepancy. These systems also include features that allow only authorized users to approve and make changes to treatment plans. The system provides critical data for quality assurance checks performed by the medical physics staff prior to treatment. These are only a few of the numerous safety features contained in the treatment management system.

In addition, treatment delivery systems and the treatment delivery machines themselves have redundant safety features. For example, there are two independent monitoring systems that measure the radiation coming out of the machine during the treatment. The intensity and uniformity of the treatment beam is monitored continuously, and an interlock will stop treatment if the values are abnormal. The system records and retains key data during the actual treatment so that, in the event of a premature shut-down, the radiation oncologist and medical physicist can precisely reconstruct the treatment and proceed to complete it accurately thereafter. Critical aspects

of the treatment are displayed on a treatment console for careful monitoring by radiation therapists during treatments. The systems require the radiation therapists or other trained clinical personnel to be physically present in the treatment room prior to treatment to correctly position the patient so that the dose is delivered accurately to the target. These are just a few of the numerous safety features in treatment delivery software and hardware systems.

It is important to note that radiation therapy devices and systems are subject to requirements, oversight and regulation by numerous government and professional organizations worldwide, including the FDA, international regulatory bodies, and international standards organizations. Radiotherapy device manufacturers adhere to the requirements of these organizations in designing and building their systems and with potential safety implications that come to their attention. Radiotherapy device manufacturers are regularly audited for compliance with regulations and fully cooperate with FDA and other regulatory and standards based inspections.

Efforts to Reduce Radiation Dose

MITA has a long history of working with its members and other stakeholders to track and reduce medical radiation. One essential element in that effort is the Digital Imaging and Communication in Medicine (DICOM) Standards which MITA manages. This is the universal standard for the interoperability of medical images, even when generated by different scanners. Thanks to these standards, imaging is, without a doubt, the most “networked” aspect of health care in the clinical setting. Importantly, the DICOM system already records dose information.

MITA collaborates to proactively tackle issues related to radiation safety. For example, in November 2009 MITA convened a stakeholders meeting in Chicago including physicians, physicists, industry and FDA officials to discuss ways to prevent future medical errors that involve radiation. MITA is also co-sponsoring upcoming CT and Radiation Therapy Radiation Dose Summits to further the education of providers and physicists on the new technologies our member companies have developed and are manufacturing. MITA members have also involved with Image Gently in development of targeted training on pediatric CT.

MITA also believes in ensuring that patients receive the right test at the right time. As part of the Access to Medical Imaging Coalition (AMIC), MITA helped to develop appropriateness criteria for advanced medical imaging included in the Medicare Improvements for Patients and Providers Act (MIPPA). We believe strongly that the integration of these criteria into clinical decision-making by physicians, will help to eliminate unnecessary images. This policy is not only helpful because it can save money, but it also ensures unnecessary scans are eliminated and that patients receive the right test at the right time for their specific symptoms. MITA is committed to working with physicians, CMS and other stakeholders to continue to examine this promising demonstration program and expand it in the future.

More recently, MITA announced its support for the President’s proposal in the fiscal year 2011 budget to develop a national dose registry and its support for the FDA *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*. MITA intends to participate fully in FDA’s efforts to reduce radiation dose.

MITA has also proposed several additional policies designed to reduce medical errors, reduce radiation dose and raise awareness of radiation dose among providers.

New Dose Check Features

Earlier this week, MITA's CT manufactures committed to including a new radiation dose check feature on their new CT products. This new feature will provide an alert when dose levels as determined by hospitals, imaging centers and clinicians are exceeded. This alert is designed to provide a clear indication that the settings for the exam resulted in a dose higher than the pre-determined reference dose for routine use.

In addition, manufacturers are committed to including an additional safeguard which allows hospitals and imaging facilities to set upper radiation dose limits to prevent CT scanning at higher, potentially dangerous radiation levels. This feature is designed to prevent hazardous levels of radiation that could lead to burns, hair loss or other injuries.

Manufactures are also committed to standardizing dose recording by incorporating the DICOM structured dose report.

Our manufactures are already working on or have implemented some of these new features and most will be able to include them on new releases of CT products and to begin deploying to their CT installed base before the end of this year. With this deployment strategy, most new CTs and similarly compatible installed base systems will include these new features during the 2012 calendar year.

MITA and our member companies stand ready to work with professional organizations, regulatory bodies, individual clinicians and other stakeholders on these features.

Reference Values

Another important and specific way that additional understanding of radiation dose can be promoted is through the development of radiation dose reference levels or reference values. The recently announced manufacturer dose check feature could utilize these values and MITA is eager to assist stakeholders in their development. Once determined, the radiation dose reference level serves as a data point at which physicians, physicists and technologists can compare the dose level of the specific procedure they are administering to a wide sample of similar tests. This information gives medical professionals an additional tool to develop and deliver optimized scans commensurate with current clinical practice.

Enhanced Training and Protocols

Training of operators of medical imaging and radiation therapy equipment on the specific machines in their facility is important to the proper use of this complex equipment. To that end, imaging and radiation therapy equipment manufacturers currently provide comprehensive training and education to the users of their equipment.

Training delivery venues include: 1) Onsite training at the customer facility using their own installed equipment, 2) Instructor led classroom training, including lab work as appropriate, delivered at the manufacturer's training center, 3) Remote instructor led training done via the internet and/or 4) Customer self-directed eLearning modules produced by the manufacturer.

Training is especially important when radiation is involved and users of imaging and radiotherapy equipment must have the appropriate clinical competence and professional training in order to leverage the additional education we provide on our specific equipment.

MITA encourages the development of training standards for hospitals and free-standing imaging facilities that purchase imaging equipment that involves the use of radiation and radiation therapy equipment. It's also important to remember that training doesn't end when our equipment is installed. Instead, it is an ongoing effort by the hospital and imaging facilities that includes continuing education, training of new employees and achieving and maintaining certifications and accreditations. We would like to work with all interested parties on these efforts.

MITA members are also eager to work with stakeholders to develop additional operational safety procedures and checklists to reduce medical errors and incorporate those new standards into our training offerings.

Error Reporting

MITA companies are currently mandated by the FDA to report serious injuries that involve their products. This is a mandate that MITA companies take very seriously and work to meticulously comply with.

MITA supports efforts to ensure standardized reporting across stakeholders in a manner that is transparent for patients, their families and physicians. As part of that effort MITA supports mandatory reporting by providers of all medical errors involving medical radiation.

As this committee considers ways to increase the frequency and completeness of error reporting, it must also carefully consider potential disincentives to under-report errors.

Accreditation and Certification

MITA is also committed to policies developed with stakeholders regarding the accreditation of advanced imaging facilities included in MIPPA and the certification of radiologic technologists. The accreditation of imaging facilities has begun this year and will continue with all providers required to be accredited by 2012. MITA supports an examination of whether this policy should be expanded to include additional facilities where radiation therapy medical devices are in use and would like to work with the Committee in this effort.

In addition, MITA supports the establishment of minimum standards for radiologic technologists who perform diagnostic medical imaging exams and deliver radiation therapy treatments.

Conclusion

Thank you for your consideration of this important issue. As the legislative process moves forward, MITA, along with physicians and patient groups, look forward to continuing to work with Congress and the administration to ensure appropriate use of medical radiation and access to life-saving technologies proven to decrease costs, prevent and treat illness, cure illness and improve quality of life for millions of Americans.

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^{viii} Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed) (2008, August 27). Newer Cardiac Imaging Machines Effective in Detecting Coronary Artery Stenosis. *ScienceDaily*. Retrieved January 8, 2009, from <http://www.sciencedaily.com/releases/2008/08/080826115909.htm>

^{ix} The Quality of Medical Care, Behavioral Risk Factors, and Longevity Growth, Dr. Grank Lichtenberg, Ph.D., National Bureau of Economic Research, June 2009.

^x Diagnostic Imaging Costs: Are They Driving Up the Costs of Hospital Care?, Molly T. Beinfeld, MPH and G. Scott Gazelle, MD, MPH, PhD, *Radiology*, June 2005.

^{xi} Ibid.

^{xii} According to Medical Expenditure Panel Survey (2004), "the average expense per night for a hospitalization in 2004 was about \$3,000 while the median per diem was about \$1,800." Accessed from http://meps.ahrq.gov/mepsweb/data_files/publications/st164/stat164.pdf on 1/07/09.

^{xiii} Goldstein, James A. et al. "A Randomized Controlled Trial of Multi-Slice Coronary Computed Tomography for Evaluation of Acute Chest Pain." *Journal of the American College of Cardiology*. 2007: 9(8)

^{xiv} Rao, Patrick M., Rhea, James T., Novelline, Robert A., Mostafavi, Amy A., McCabe, Charles J. Effect of Computed Tomography of the Appendix on Treatment of Patients and Use of Hospital Resources. *N Engl J Med* 1998 338: 141-146

^{xv} <http://www.hps.org/publicinformation/ate/q435.html>

^{xvi} "The ALARA Concept in Radiographic Dose Reduction," *Radiologic Technology*, November 2004.

^{xvii} "In Planning CT Dose Reduction, One Size Does Not Fit All," *Diagnostic Imaging*, November 1, 2003.

Mr. PALLONE. Thank you, Mr. Fisher.
Mr. Donahue.

STATEMENT OF JOHN J. DONAHUE

Mr. DONAHUE. Thank you, Chairman Pallone, Congressman Whitfield.

My name is John Donahue and I am grateful to be here to discuss the issues surrounding ionizing radiation in medicine. I want to begin by expressing my profound admiration for the courage of the Parks Family.

I am here as the vice-chairman of Medicalis. Medicalis is a leading innovator of technology and clinical solutions focused on improving access to high-quality, safe, clinically-appropriate, advanced diagnostic imaging. We are a company founded by the radiologists and information technologists of the Brigham and Women's Hospital in Boston. We provide physicians at the point of ordering with web-based radiation safety and clinical appropriateness decision support.

By way of background, I have been in the health care, the international health care industry for over 25 years in the pharmaceutical vaccine and the radiology industry. In the late 1990s, I co-founded and acted as president and CEO of one of the nation's first and the largest radiology benefit management companies. I have had the opportunity to interact extensively with CMS, MedPAC, the GAO, Congressional offices and many of the stakeholders in this area on an array of imaging issues.

Diagnostic imaging is rife with many health policy and Federal legislative opportunities. I am hopeful that after today's hearing, we will all agree that radiation safety in imaging is a measurable and very serious issue but there are specific steps that we can take to mitigate the risk.

Radiation safety has been very much in discussion since 1895 when a new kind of light, the x-ray was discovered. In July of 2005, the National Academy of Science has issued a seminal study that examined health risks from exposure to low level ionizing radiation. Today this study is commonly referred to as the BEIR VII report or the Biological Effect of Ionizing Radiation report. The watershed conclusion was that any level of ionizing radiation can induce a carcinogenic effect. The report showed that a single CT of the abdomen emitting 10 milliSieverts of ionizing radiation increases the risk of induced cancer to 1 in 1000 times. Further and importantly, cumulative dosage totaling 100 milliSieverts can ratchet up this carcinogenic risk to 1 in 100 times.

It is also important to note that although radiosensitivity values vary dramatically by body tissue as well as by gender and by age, studies have shown that there are meaningful dose estimates that can be measured. For example, the Cleveland Clinic submits that an abdominal CT emits roughly 10 milliSieverts of radiation, a Cardiac PET 15, a CT urographic study 44, while a plain chest x-ray emits less than .1 millisieverts.

In 2006, I helped lead a radiation safety dosage initiative and awareness program. The results were startling and they were highlighted extensively in the Wall Street Journal. Firstly, some individuals received radiation exposure more than 1000 percent higher

than recommended guidelines. And secondly, one patient received 341 CT scans over an 18-month period bringing the radiation exposure level to almost 1000 milliSieverts.

In 2007, I presented yet another radiation safety initiative focused on the Medicare population. In this particular study over a 12-month period, almost 20 percent of the medical population, of the Medicare population receive radiation exposure that exceeded the BIER VII radiation recommended levels.

Diagnostic imaging is an extraordinary clinical tool. We want to encourage and expand the appropriate and the safe use of diagnostic imaging but the evidence appears to be incontrovertible that patients are all too often exposed to unnecessary level of ionizing radiation.

I believe the solution is to do four things. Firstly to ensure that every advanced imaging study is clinically proven by evidence and that it is not redundant. Secondly, to measure and report on individual cumulative milliSievert dosage, and present this ionizing history to physicians at the point of ordering. Thirdly, I believe we should require recommendations of viable clinical alternatives to enhanced radiation risk when they exist. For example, could an ultrasound, a lab test or some blood work be sufficient for an initial diagnosis? Finally, the fourth is I believe that once these tests pass these three criteria that they should be performed in facilities by physicians and by RAD techs who are accredited and trained, and that the equipment is assured to be set at the correct specifications.

My company, Medicalis, is able to deliver clinical appropriateness and radiation safety today. We continuously survey and present available patient information to physicians at the point of ordering, including an individual-specific radiation history dosage. We also evaluate the clinical appropriateness of the test and present alternative recommendations if radiation safety sparks a concern.

In 2010, we have no excuse but to leverage available clinical evidence, innovative technology and regulatory policy to assure that all Americans receive clinically-appropriate and safe advanced diagnostic imaging. I would respectfully suggest that Congress encourage CMS to encourage a web-based or to include a web-based, clinical decision support in radiology safety program in the upcoming radiology pilots.

In addition and finally, I want to commend the Food and Drug Administration's unveiling of its recent radiology initiative, specifically, the two underlying principles of appropriate justification of a radiation procedure and the optimization of the radiation dosage. These two issues address many of the concerns that I have raised in this testimony and we look forward to working with the FDA and other imaging stakeholders as this effort moves forward.

I want to thank the chairman and I want to thank the entire committee for your focus on this issue, and I would be pleased to answer any questions.

[The prepared statement of Mr. Donahue follows:]

House Committee on Energy & Commerce
Subcommittee on Health
Hearing on Medical Radiation: An Overview of the Issues
February 26, 2010

Chairman Pallone, Ranking Member Deal and Members of the Subcommittee, my name is John Donahue and I am honored and grateful to be here to discuss the issues surrounding ionizing radiation in medicine. I am here as the Vice Chairman of Medicalis Inc. Medicalis is a leading innovator of technology and clinical solutions focused on improving access to high quality, safe, clinically appropriate and affordable diagnostic imaging care. We are a company founded by the radiologists and health technologists at the Brigham and Women's hospital system in Boston; we provide on-line, point of order, web-based radiation safety and clinical appropriateness decision support guidance to physicians.

By way of background, I have worked in health care for over 25 years in the international pharmaceutical, vaccine, biotech and clinical laboratory industry. In the late 1990's, I co-founded and was the President and CEO, of one the nation's first and largest radiology benefit management companies. In that capacity, I had the privilege to testify in 2005 before this Committee on imaging policy. Since that time, I have had the opportunity to interact extensively with CMS, MedPAC, GAO, Congressional offices and many of the industry stakeholders on an array of imaging topics. I also lecture at the Harvard School of Public Health on imaging, medical management and health policy matters.

Diagnostic imaging is rife with many health policy and Federal legislative opportunities. I am hopeful that after today's hearing, we will agree that radiation safety in imaging is a measurable and very serious issue, and that there are specific steps that the Federal government and the industry can take now to mitigate risk of over-exposure. Requiring on-line radiation safety guidance and clinical decision support at the point of ordering for all Medicare and Medicaid patients would meaningfully lower the incidence of cancer and improve health outcomes for patients as well as reduce health care spending in the public health programs.

Radiation safety has been in discussion since 1895 when "a new kind of light", the X-Ray, was discovered. In the 1990's, our Food and Drug Administration (FDA) suggested a methodology for recording X-ray absorption. In late 2001, FDA again issued a notice to all health-care professionals emphasizing the need to minimize radiation exposure in pediatric patients. In July 2005, the National Academy of Sciences issued a seminal study that examined health risks from exposure to low levels of ionizing radiation. Today, this is commonly referred to as the BIOLOGICAL EFFECT OF IONIZING RADIATION or the BEIR VII report. The watershed conclusion was that any level of ionizing radiation can induce a carcinogenic effect. The report showed that a single CT of the abdomen emitting 10 milliSieverts (the most common unit of measure, "mSv") of radiation can result in radiation induced cancer 1 in 1000 times. Further, cumulative dosage totaling 100 mSv can ratchet this carcinogenic risk up to 1 in 100 times. Statistically, as exposure to mSv increases so does the likelihood of cancer.

It is important to note that radiosensitivity varies by body tissue as well as by the gender and age of the patient. Studies have shown meaningful dose estimates can be measured. For example, the Cleveland Clinic submits that an abdominal CT emits roughly 10 mSv, a Cardiac PET - 15 mSv, a CT urographic study - 44 mSv, while a plain chest Xray emits less than .1 mSv.

In 2006, I helped lead a radiation dosage safety and awareness program, in conjunction with a leading health insurer. The results were startling. They highlighted widespread radiation safety concerns and were reported extensively in the Wall Street Journal:

1. some individuals received radiation exposure levels more than 1000 percent higher than that recommended by medical guidelines, and
2. one patient, received 341 CT scans over an 18-month period, bringing the radiation exposure level to 993.3 mSv.

In 2007, I presented yet another study on imaging appropriateness and radiation safety to one Medicare Advantage plan. The conclusion was that in one 12-month period, almost 20 percent of this population received radiation exposure exceeding the first BEIR VII threshold of 10 mSv. Additional studies show that there are still widespread misconceptions amongst ordering physicians. One example is that shorter scanning times result in lower dosage. In fact, the opposite can be true because time and CT radiation dose are not proportional.

Diagnostic imaging is an extraordinary clinical tool and the benefit of diagnostic imaging in this context almost always exceeds the risk of induced carcinogenic effects.

However, the studies cited above show incontrovertibly that patients are too often needlessly exposed to dangerously high levels of ionizing radiation that can induce the adverse outcomes of carcinogenesis. I would point out that, in addition, the GAO, MedPAC and CMS have concluded that imaging utilization is growing far ahead of overall health inflation and much of this growth is not clinically warranted and is unsupported by clinical evidence.

I believe the solution is to leverage the clinical evidence, measurement techniques and web technology available to us today to:

1. ensure every advanced imaging exam is clinically supported by evidence and is not redundant
2. measure and report on individual cumulative mSv dosage and present this ionizing history to physicians at the point of ordering
3. require recommendations of viable clinical alternatives to enhanced radiation risks when they exist. For example, is an ultrasound or is a blood or lab test sufficient for an initial diagnosis?
4. ensure that these tests, once deemed clinically supported and safe, are performed by a physician and at a facility that adheres to the highest levels of clinical quality.

My company, Medicalis, is able today to deliver clinical appropriateness and radiation safety guidance to physicians, thereby improving health care outcomes, materially reducing radiation risk, and meaningfully lowering costs by eliminating unnecessary tests. Medicalis has a health data integration tool that links into lab, pharmacy, utilization management, archive systems, electronic medical records and claims data sets. We continuously survey all available patient data, including their personal ionizing radiation history. When physicians use our point of ordering, decision support, web based tool to request an imaging exam, we immediately present clinical evidence to guide that physician to the clinically appropriate test in the form of decision support. We also immediately present an intuitive patient-specific, risk assessment of radiation exposure: by the actual precise absorbed dose for a procedure when available, or by an algorithm considering patient age, gender, and body part based on the estimated mSv dosage for each procedure. If there is further ancillary risk, such as MR gadolinium contrast in certain renal conditions, we immediately present the information to the physician and offer alternative clinical action. Critically, all of this information becomes imbedded into the patient's electronic medical record.

In 2010, we have no excuse but to leverage available clinical evidence, innovative technology and federal legislative and regulatory policy to provide all Americans with clinically appropriate, radiation safe and affordable imaging care. I would respectfully suggest that Congress encourage CMS to include web-based, clinically proven decision guidance with actual radiation safety capabilities into the upcoming radiology pilot initiatives and seriously consider any additional legislation to address these very serious policy concerns.

In addition, the Food and Drug Administration should be commended for the unveiling of its recent, "Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging." This effort will focus on the safe use of medical imaging devices, support informed clinical decision-making and increase patient awareness of their own exposure. Specifically, FDA has highlighted two underlying principles: appropriate justification of the radiation procedure and optimization of the radiation dose. This effort addresses many of the concerns raised in my testimony and Medicalis looks forward to working with the FDA and other industry stakeholders as this effort moves forward.

I want to thank the Chairman and the Subcommittee again for your focus on the medical radiation issues. I would be pleased to answer all questions and to provide any further information.

Mr. PALLONE. Thank you, Mr. Donahue.

Thank all of you. We will take some questions now.

Let me start out by saying that Dr. Michael Hagan, I guess, is here to accompany Mr. Mizrach. That is you? Raise your hand, OK, and that would be if we have any questions about the VA in general, I understand.

And then I also would ask unanimous consent to enter into the record a statement by our Chairman Emeritus John Dingell. Without objection, so ordered.

[The prepared statement of Mr. Dingell follows:]

Statement of the Honorable John D. Dingell
Subcommittee on Health
Hearing on “Medical Radiation: An Overview of the Issues”
February 26, 2010

Thank you, Mr. Chairman for holding this important hearing.

Recent newspaper stories have highlighted the consequences of negligence associated with the use of medical radiation devices and therapies. Patients today receive far more radiation than ever before. With the ever increasing number of devices and therapies that have transformed the diagnosis and treatment of life threatening diseases, and their more frequent use, comes the realization that patients are sometimes subject to radiation overexposure.

While rare, accidental exposure to excessive amounts of radiation can cause injuries, such as skin burns, hair loss, and cataracts, and can increase a person’s lifetime cancer risk.

I appreciate the fact that today’s hearing will allow us to focus on this important issue. It affords us the opportunity to ask some very critical questions relevant to the safety of medical radiation.

- Are medical radiation technicians and professionals adequately trained to perform the critical tasks we expect them to perform?
- Are hospitals providing the necessary financial support and personnel to operate the sophisticated devices safely?
- Are manufacturers doing all they can to develop reliable equipment, and are they providing proper training support for facilities that purchase their products?
- Are our federal regulators, more specifically the Food and Drug Administration and the Nuclear Regulatory Commission, doing what must be done to ensure the safety of American patients that benefit from these medical devices and therapies?
- Are our laws and regulations keeping up with an increasingly complex medical radiation device market?
- Do we have adequate error reporting systems so that we can more fully understand their underlying causes?

The stories we have all read about clearly demonstrate that more can and should be done to ensure the safety of American patients. I was encouraged by FDA’s recent announcement that it plans to take steps to reduce unnecessary radiation exposure from

certain medical imaging procedures. I hope this is the first in a series of steps the Agency takes on this issue. The uncertainty surrounding medical radiation diagnostics and therapies is not good for the health of patients. Nor is it good for the advancement of science.

Let me be very clear. I am convinced that the benefit these devices and therapies provide far outweigh the risks associated with them. They can be credited with saving countless lives and prolonging many others. They have also transformed the care provided to patients in a way that is more accurate, less invasive, and much more efficient. However, seeking ways to make their use safer for patients should be a never-ending quest.

Mr. Chairman, I look forward to hearing from today's witnesses. I also look forward to working on this issue in the future.

Thank you. I yield back the balance of my time.

Mr. PALLONE. I am going to start the questioning and I wanted to start with Ken Mizrach if I could. Again, the reason why your testimony is so valuable in my opinion is because you at the VA hospital in New Jersey went through a situation where there were problems. You closed the facility. You came back and corrected them and so I think that example is sort of a good one, and in part what I am asking is whether these changes that you have made, you know, could be utilized at other facilities? I mean that is really what I am trying to get down to but let me just say, Mr. Mizrach, you mentioned in your testimony that you will require continuous education for all staff specifically with respect to the technology and equipment. Can you elaborate on this in more detail and explain how you think this is going to work in practice and, I guess, also whether it will be useful for other hospitals.

Mr. MIZRACH. Well, I think there needs to be a constant, continuous education on any new piece of equipment in a medical center, whether it is in radiation oncology or radiology department or audiology and speech. There are programs available nationwide constantly being offered. We need to make sure that our specialists are certified and trained before they have any opportunity to use the equipment. Recently, as we are getting ready to open our program, we brought in the manufacturers to work with our staff to observe simulations and that was part of the process, and before we get the green light to open, we need to make sure that everyone is equipped. I want to know that my airline pilot is ready to fly that new piece of equipment before I get on that plane and there should be no difference in being treated in a medical center.

Mr. PALLONE. Now, you mentioned conducting routine tests of the machines to make sure that the therapy you are providing is correct and safe. One of the recent articles in the New York Times highlighted a hospital that has been over-radiating patients for the past 5 years, and their regular system checks did not catch the error. So can you just elaborate a little more on this aspect of the quality assurance plan and how these types of tests work and again, how they would be, you know, help prevent situations in other hospitals?

Mr. MIZRACH. I would really like to defer that to Dr. Hagan who really has the expertise.

Mr. PALLONE. Sure, all right, he will have to come up, I guess, and take your place there. I don't know where or use one of the mikes.

Dr. HAGAN. Mr. Chairman, after East Orange, shortly after East Orange the VA nationally required ACR accreditation for all radiation oncology facilities within the VA. Nationally, fewer than 20 percent of radiation oncology practices are ACR accredited. This requirement for accreditation comes with some teeth.

In the last year under signature by the principal deputy under secretary, any finding by a surveyor at a VA site now must be corrected. And the authority for that correction goes up to the network director, and the network director is required to report through my program office to the under secretary that each item has been corrected so that puts the quality control loop.

To answer your specific question though about the physics oversight for radiation oncology, it is a little bit different although

when ACR evaluates, they evaluate both with medical physics and the process with the radiation oncologists. Most of our centers put patients on NCI-sponsored trials and so they fall under quality assurance program for the Radiologic Physics Center. You have heard that mentioned by a couple of panelists today. It is a federally-funded, undergrad center out of M.D. Anderson.

Prior to initiating treatment again in East Orange, our PC paid a visit and went through their very extensive evaluation of the linear accelerator at that facility and so they have been surveyed with almost 36 hours of continuous operation with a physicist going through each of the planned operations and actually it is a result of that initial evaluation that we are going to hold on treatment of the first patient until all of the issues that were found by the RPC have been resolved.

Mr. PALLONE. I guess going back to my initial statement, to what extent is what you are doing now something that you would see that we should apply nationwide or to other hospitals not in the VA system?

Dr. HAGAN. That is an excellent question and RPC is mandated to support with onsite evaluations, all centers place patients on NCI-sponsored trials. To be able to expand that kind of service nationwide would require an order of magnitude increase in the size and facility of like RPC. Actually, it would jeopardize their ability to perform their mandate which is to support clinical trials but to use RPC as a model and then fund a similar organization that can do that level of observation on a routine basis in each center should be mandatory.

Mr. PALLONE. OK, thank you very much.

I don't even know what my time is here so I have another 2 minutes. I am not sure that is accurate. I think I may have given myself more time but in any case the, let's see, I am going to ask this of Dr. Herman, I guess, if I could have shortened this with the time.

In one of the New York Times articles in order to qualify for a clinical trial in radiation therapy, the institution has to submit to enhanced testing to make sure that they were delivering therapy properly. And I guess a lot of the institutions failed those tests according to the New York Times, but in the report by your association, Dr. Herman, you also said this was a sobering statistic, and I agree, and that the tests are quite rigorous but still when our nation's top institutions apply to a clinical trial and often fail we should wonder what is happening. So I wanted to ask you do you think that this is a sign of a larger problem and I don't know, I just wanted someone to respond to that. I guess it could be you, Dr. Herman, sure.

Mr. HERMAN. It is certainly an indication that it is difficult to carry out IMRT treatments. One of the things the sentence that follows the part about the sobering statistic in that same report suggests that there is a larger consideration with the commissioning portion of the systems that comes before the clinical use. So the details of the algorithm and some of the other things that can create additional variations and some of the results, some of the cases that didn't pass in the first, the RPM phantoms, were also due to not using the entire team to do the treatments. So I think one of

the things that would be helpful is to have the phantom go through the entire identical process to what a patient goes through as opposed to sometimes having physicists try to do the whole thing because you are not taking advantage of the entire team component.

Mr. PALLONE. OK and, Ms. Hayden, you talked about all these variations in terms of education, standards, accreditation from one State to the next, and you obviously mentioned the CARE bill that you would like to see that promulgated. It seems to me frankly that, you know, what you suggested is probably, you know, it may be one of the most important things to do because the technicians are such an important part of this so I just I don't know if you wanted to comment any more about, you know, the importance of national standards but I have to say that it was really disturbing to me to read that there was so much variation from State to State. And I don't know if you wanted to hit anything more about it but I just thought that that was really sobering more than anything else.

Ms. HAYDEN. Of course, Chairman Pallone, I appreciate this opportunity to speak again on behalf of the ASRT as well as on behalf of the radiologic technologists that administer radiation therapy and do the radiologic technology medical imaging exams. There is—it is very sobering. The radiation therapists in my case which is what I am, we are the last line of defense for the patients. We are the safety net for the patients. We are the ones that are turning on that machine. We work in collaboration and we follow the prescription from the physician. We work hand-in-hand with physics. I feel like I want to hold hands at the table but certainly the CARE bill itself is just commonsense to have educationally prepared, clinically competent practitioners, radiologic technologists is what we like to be referred as, to actually deliver this care for patients. Patients should be the number one focus of this and I am awfully happy to have the opportunity to comment.

Mr. PALLONE. Well, let me just ask this and this will be my last question. If we were to implement, let's say we were to pass the CARE bill, I guess you would have to—you couldn't—you would have to make it pro, you know, moving forward. You couldn't make it retroactive presumably. How long would it take before, you know, you would be able to have enough people to perform these tasks that would meet the standards of the CARE bill? I mean are we in position that we would have to say, you know, 2, 3, 4 years from now before we could actually have enough people that would meet the standards?

Ms. HAYDEN. Yes.

Mr. PALLONE. Sure.

Ms. HAYDEN. We actually have timeframes. There will not be a shortage in regards to the people that will actually be performing examinations with the CARE bill or the passage of the CARE bill. As a total opposite, it also will help save money in regards to not having repeated images and things of that nature. And in addition to that there is effective dates to the CARE bill and so you would, you know, definitely follow that and I have it in my hand here for you but we just want to be sure, the ASRT, that the people providing care to patients that deliver radiation therapy and medical imaging have minimal education requirements and are competent.

Mr. PALLONE. It makes perfect sense to me.

Mr. Whitfield.

Mr. WHITFIELD. Thank you.

Ms. Hayden, I would just like to expand a little bit on Chairman Pallone's questioning. You indicated you felt like you should be holding hands with Dr. Herman there.

Ms. HAYDEN. We do all the time. I work at night with physics all the time.

Mr. WHITFIELD. But to help me have a little better understanding of this, you are at M.D. Anderson, correct?

Ms. HAYDEN. Yes, sir.

Mr. WHITFIELD. OK so the team that is involved in the treatment or the diagnostic work would be you, the medical physicist and the radiation oncologist, would that basically be the team for treatment?

Ms. HAYDEN. We also have medical dosimetrists as well and radiation therapists.

Mr. WHITFIELD. OK and now what is your educational background? What is required to be a radiation therapist? Do you have to have an undergraduate degree and then?

Ms. HAYDEN. Well, you ask—my personal credentials is I have a Baccalaureate in Science degree in radiation therapy technology from Michigan, Wayne State University, and so but there is different qualifications for radiation therapists now as you heard within 17 States. I received registry in my certification exam I passed through the American Registry of Radiologic Technologists which then makes me able to then be a qualified radiation therapy professional.

Mr. WHITFIELD. Now, in some States could you be a radiation therapist with just an undergraduate degree?

Ms. HAYDEN. Yes, you can be radiation therapist with any sort of qualification in the States that don't regulate it. I worked in Michigan and practiced there for over 10 years, sir, and I worked side-by-side by people because Michigan is an unregulated State for radiation therapy that did not have credentials. And I must say it was very painful and I made sure that our patients were cared for but it is very—it is not a good practice to be able to have practitioners that have all sorts of varying credentials or non-credentials, delivering radiation therapy care.

Mr. WHITFIELD. So, Dr. Williams, are you and Dr. Herman very much concerned about that as well?

Dr. WILLIAMS. Yes, sir.

Mr. WHITFIELD. Are there 17 States that does not require licensure, is that what you said?

Dr. WILLIAMS. I am not sure of the exact number, sir, but there are number of States that don't require any licensure whatsoever.

Mr. WHITFIELD. So then the hospital or facility that hires them, they just have the free reign to hire whoever they want to, is that correct?

Dr. WILLIAMS. Yes, Congressman.

Mr. WHITFIELD. And then, hopefully, they have the training program of some kind and go from there.

OK we have some work to do.

Dr. Amis, in your testimony you indicated that MIPPA's accreditation mandate should apply to all facilities including hospitals and I was wondering what other settings besides hospitals are not covered by the MIPPA requirement?

Dr. AMIS. It is my understanding that basically there is hospital-based and then there are independent centers and that MIPPA only does apply to the free-standing, non-hospital-base centers, and we feel that if there is going to be mandatory accreditation, it should involve all centers so that we all have the same standard of care for patients.

Mr. WHITFIELD. Yes, OK, so free-standing has to meet the requirements and the hospitals are not required to do so.

Dr. AMIS. That is correct and my understanding under the MIPPA.

Mr. WHITFIELD. OK, now, Mr. Fisher, you and Mr. Donahue are involved in a different way in this area we are talking about. You represent some of the medical device manufacturers.

Mr. FISHER. Yes.

Mr. WHITFIELD. And you also Dr. Donahue, I mean Mr. Donahue?

Mr. DONAHUE. No, I represent a medical management company that focuses on providing radiation safety to physicians when they order advanced imaging.

Mr. WHITFIELD. So you are a contract manager then for a facility?

Mr. DONAHUE. Yes, we are a health care information technology and a clinical company.

Mr. WHITFIELD. OK.

Mr. DONAHUE. And we work with large hospitals like the Brigham and Women's system. We work with General Electric and increasingly are working with health insurers throughout the country who are again very focused on clinical appropriateness and radiation safety.

Mr. WHITFIELD. Yes, I remember in your testimony you talked a little bit, I believe, about individual radiation history.

Mr. DONAHUE. That is correct.

Mr. WHITFIELD. And does your company actually do that now?

Mr. DONAHUE. Yes, sir, we do. It is there are metrics available, readily available that can create a very accurate measure of radiation dosage when it is applied and it is critically important to track this over a long period of time to assure that cumulative dosage doesn't put a patient into carcinogenic risk. So we as a company perform that service. We track dosage. We measure it and embed that information into the electronic medical record of the patient so it is there for the life of the patient irregardless of the insurer or if they move into a Medicare environment.

Mr. WHITFIELD. Isn't the dosage that a patient receives is it required that that be in the medical record, Dr. Williams or Dr. Herman?

Dr. WILLIAMS. No, sir, not at this time.

Mr. WHITFIELD. It is not. So if a patient comes to a facility that you manage and you don't know anything about what they have been exposed to so you are talking about only while they are a patient at the area you are managing.

Mr. DONAHUE. Yes, sir, but what we do for our health insurers for example, is this is such a concerning issue we do a forensic analysis based on their claims data and based on any available clinical data to try to create a history of ionizing radiation. So for example, we can delve into a multimillion data set of claims data and put together how many CTs, what body part and what the cumulative exposure would be for a patient. So we feel so strongly enough about the safety issue that it is worth the effort to go back and to do this and then on an ongoing basis every new imaging procedure gets measured and tracked. And importantly, if there is a situation where a patient becomes at enhanced risk that that next incremental study could present a carcinogenic risk, the physician is immediately alerted electronically and provided with alternative action to consider.

Mr. WHITFIELD. And how many facilities do you all manage?

Mr. DONAHUE. We are a relatively young company. Our largest facility is the Brigham and Women's Hospital System in Boston which is we manage inpatient and outpatient very extensively but this approach is gaining a lot of attention and traction throughout the country.

Mr. WHITFIELD. Right.

Ms. HAYDEN, is it required at M.D. Anderson that on the medical record the dosage of radiation given to a patient be on the medical record?

Ms. HAYDEN. Sir, I respectfully in regard to diagnostic imaging which is not a department that I work in I can get back that answer to you in regards to my own facility. In regards to radiation therapy, yes, the dosage is recorded for radiation therapy.

Mr. WHITFIELD. Oh, OK for radiation.

Ms. HAYDEN. Not for, yes.

Mr. WHITFIELD. OK, OK, well, Mr. Chairman, I see I started with 5 minutes and I now have 10 minutes and 50 seconds to go so.

Mr. PALLONE. Yes, I think our clocks are a little off.

Mr. WHITFIELD. But I would like to ask unanimous consent however to enter into the record a letter from the Society of Interventional Radiologists simply on their views on this issue and also from the Radiopharmaceuticals views on this issue.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. WHITFIELD. Thank you all very much for your time and your testimony today. We really appreciate it.

Mr. PALLONE. Thank you, Mr. Whitfield.

Did you want to add something, Mr. Donahue? No.

Let me say this, I mean this has been incredibly useful and thought provoking. As I mentioned to the previous panel we will undoubtedly get back to you with additional written questions, usually about 10 days from now and then we will ask you about it but I got to be honest and this is in no way meant to be offensive. As much as valuable as your responses were in many ways I felt that we ended up with more questions as a result of your responses. In other words, I think it is very likely that we are going to have to have an additional hearing on this subject because so many questions came up today that, you know, that I didn't even think about

initially, and if we are going to develop legislation, well, I shouldn't say develop. We already have the CARE legislation. I think before we move on that or, you know, have a legislative hearing or draft something else that we probably will need to have an additional hearing because I just had so many questions that came out of this today, and but really you were extremely helpful in us trying to get to the bottom of some of the problems out there. And not to suggest that again, we are not suggesting that we don't want people to proceed with CAT scans or other diagnostic tools or other forms of radiation because we know how important that is but there are just a lot of questions I think that need to be answered.

So thank you very much and we will conclude the hearing today but I can't emphasize enough how valuable this was, and without objection, the hearing is concluded.

[Whereupon, at 2:40 p.m., the Subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**U.S. Representative Kathy Castor
Committee on Energy and Commerce – Subcommittee on Health
Hearing on Medical Radiation
February 26, 2010**

- Mr. Chairman, thank you for holding today's hearing on such an important issue.
- Advances in radiation therapies and screenings have undeniably saved lives and enabled us to detect potentially devastating conditions early enough to save lives – a benefit that we did not have in generations past.
- Radiation technology and equipment continues to grow and advance quickly. And while this is exciting for the future of health care, it comes with added concerns and safety issues for patients that are the first to undergo some of the latest treatments.
- Not long ago in my hometown of Tampa, the Moffitt Cancer Center, a premier Cancer Institute in Florida, and one of the best nationwide, had an extended series of errors resulting from a miscalibrated machine to treat cancer patients.
- Between 2004 and 2005, 77 brain cancer patients were overradiated because a newer and more advanced machine had not been set up correctly. The problem wasn't discovered until inspectors from the Radiological Physics Center, a federally financed testing service came in for an inspection.
- The director of the Radiological Physics Center said that if the inspection occurred earlier or if centers had a regular practice which included inspections such as those which they performed, these errors could have been avoided.
- An article in today's New York Times highlighted another incident in Florida, which was very concerning. Unlike the accidental errors in Tampa, a radiation center in Melbourne Florida, associated with one of the State's largest physician practices was accused of fraudulent activities on two fronts.

- First, Medicare requires certain cancer treatments be administered only when the patient's radiation oncologist is present or nearby. However the physician group submitted claims for more than 200 treatments when radiation oncologists were not only absent from treatment, but out of the country.
- Another accusation came when a patient was overradiated and almost died. A 51 year old woman was told by her doctor, "I'm sorry, but yes, we overradiated you." It was alleged that doctors may have had a financial interest in providing certain more advanced treatments in their own centers, for which they stood to receive a financial benefit. These treatments were more lucrative for the doctors, but may have been medically unnecessary for the patients.
- It is critical that we take a closer look at modern radiology screenings and treatments. We must work to ensure that unfortunate accidents no longer occur and that centers are testing more diligently for potential errors in dosages.
- If there are cases where terrible and dangerous treatments are given to patients due to neglect or fraudulent activities, physicians must be held accountable.
- I look forward to investigating this issue and welcome input from those who have personal experiences with treatment as well as experts in radiology, radiation oncology, radiological physics and others with expertise in the field.

**Opening Statement
Congresswoman Tammy Baldwin
Hearing on Medical Radiation: An Overview of the Issues
February 26, 2010**

Thank you, Mr. Chairman, for convening this hearing on medical radiation. My primary concern, of course, is the health and safety of my constituents, and all Americans. As always, we want to strike the right balance. We want to ensure safety while prompting innovation, like the development of technologies that target radiation more accurately, assuring the right dose, to the right location, at the right time. I have the privilege of representing a number of companies, small and big, new and established, that are developing innovative new radiological therapies and manufacturing state of the art imaging devices.

The issue of medical radiation and human health is complicated. There are so many actors involved. There are doctors and radiological technicians in the health care system, the federal and state government

payers and regulators, and the private sector manufacturers of devices and programmers of software.

To make a diagnosis, we rely on the doctors, technicians and manufacturers to work together to develop and abide by appropriateness criteria. To treat a disease, we again rely on health care providers and manufacturers to develop treatment plans that target the disease while minimizing negative effects to the patient's overall health.

To prevent mistakes, and to confront mistakes after they happen, we rely on the FDA to oversee the manufacturers; CMS to oversee the providers; and our states to oversee the professional personnel.

And in the private sector, we see consistent innovation to refine and perfect radiation in health care. The imaging industry has dedicated itself to reducing the level of radiation that is necessary while still providing doctors with the images they need to make a diagnosis.

And radiation therapy technology is improving as we speak. Tomo Therapy, a company in my district, increases the effectiveness of radiation therapy with integrated imaging technology. It gives clinicians increased flexibility, allowing them to change treatment on a daily basis as the anatomy of the patient's malignancy changes and heals. Doctors are then able to reduce unnecessary radiation to healthy cells.

My heart goes out to those testifying today, and the many Americans they represent, who have suffered harm. I hope we can take a careful look at this issue to ensure that we use the medical tool of radiation to do the most good for human health.

Again, thank you Mr. Chairman for convening this hearing and I yield back.

STATEMENT OF THE HONORABLE JOE BARTON
RANKING MEMBER COMMITTEE ON ENERGY AND
COMMERCE

HEALTH SUBCOMMITTEE HEARING:
MEDICAL RADIATION: AN OVERVIEW OF THE ISSUES
February 26, 2010

Thank you, Mr. Chairman for holding this hearing. I also want to thank our distinguished witnesses for coming here today to educate the Committee on this important topic.

Medical radiation involves both radiation therapy and medical imaging. The medical community uses radiation therapy to treat cancerous tumors, including brain cancer, breast cancer, lung cancer, and prostate cancer, just to name a few. They use medical imaging, like CT scans and mammograms, to find those tumors and identify other problems. It is clear that the overwhelming majority of

Americans who receive radiation therapy and medical imaging benefit greatly, and thousands of lives are saved each year because of these treatments and procedures.

This hearing will focus in part on tragic events associated with radiation therapy. These events raise legitimate questions that we need to explore. My hope is that the Members of the Committee and the public will listen to the witnesses without preconceptions. We must examine the issues associated with radiation therapy and medical imaging, and if there are problems to be addressed, we need to work with the manufacturers and providers to do so. However, as we examine these issues, it is important that no one comes away from this hearing thinking radiation therapy and medical imaging are not safe. Too many lives are at stake.

As an engineer, I am particularly interested to hear from the manufacturers how these life-saving devices work. I am also interested in hearing from the various provider groups on the training associated with operating these devices and how the different professional societies develop criteria so these devices are operated safely.

These are complex issues because there are so many moving parts, both literally and figuratively. I look forward to listening to the testimony of our witnesses and learning more about this important topic. I yield back.



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February 24, 2010

The Honorable Nathan Deal
Congress of the United States
House of Representatives
Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Congressman Deal:

RE: Hearing on “Medical Radiation: An Overview of the Issue”

The Society of Interventional Radiology (SIR) appreciates the opportunity to submit comments to the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, for the hearing on “Medical Radiation: An Overview of the Issues.” We commend you for convening this important hearing.

SIR is a professional medical society representing more than 4,500 practicing interventional radiology physicians, clinical associates, PhD scientists, and medical physicists whose mission is to improve the health of the public through pioneering advances in image-guided therapy.

Interventional radiology is the medical specialty credited with pioneering modern minimally invasive medicine—medical treatment without scalpels—by reaching the source of a medical problem through blood vessels or directly through a small nick in the skin to deliver a precise, targeted treatment. Interventional radiologists are responsible for much of the medical innovation and development of minimally invasive treatments that are commonplace today. From the invention of angioplasty and the catheter-delivered stent, which were both first used to treat peripheral arterial disease in the legs, to drug-eluting stents, balloon angioplasty, catheter delivery systems and clot-removing devices of today—these specialists continue to shape and change the medical landscape and improve patient care. IR treatments delivered by board-certified experts can deliver solutions with less risk, less pain and less recovery time than traditional surgery.

Interventional radiologists use ionizing radiation (fluoroscopy) as well as other imaging modalities in the performance of their procedures. They have demonstrated competency

through their American Board of Medical Specialties (ABMS)-sanctioned Board Certification. All interventional radiologists receive extensive training in radiation physics, radiation biology, and radiation safety in their residency.

SIR is committed to radiation safety and has a long history of advocating for radiation dose reduction for patients. For the past thirty-five years, SIR has taken a leading role in measuring and assessing radiation dosage; developing educational programs on radiation safety, radiation protection, and reduction of skin dosage; developing radiation safety guidelines; and promoting the safety of patients and health care professionals for image-guided therapies. (1, 2).

We agree with the fundamental principles of ALARA (as low as reasonably achievable) and support efforts to ensure the lowest possible dose. SIR's position is clearly stated in our *Statement on Radiation Safety*:

Those who use radiation must be adequately trained in radiation safety, radiation physics, the biologic effects of radiation, and injury prevention to ensure patient safety. The use of radiation in diagnosing and treating patients has significantly advanced the field of medicine and saved or extended countless lives...The use of radiation, however, is not without risk...Those who use radiation must be adequately trained in radiation safety, radiation physics, the biologic effects of radiation, and injury prevention to ensure patient safety. This training is standard in radiology and interventional radiology training programs. (3)

For an individual patient, radiation risks, while real, must be interpreted in the context of relative risk and benefit. Certainly, cumulative dose is important as well and all efforts must be made to minimize both. But, these efforts must be balanced against the expected benefit of any interventional or diagnostic procedure. (4)

After fluoroscopy was developed at the turn of the last century, it was applied widely in and out of the medical space. After the discovery that X-rays could cause injury, its use was constrained in medicine and a specialty called Radiology was created to manage this beneficial but potentially harmful tool. The risks of radiation are not a new concept for our discipline. With more advanced technological platforms, increasingly complex procedures, and dissemination of use outside of our discipline, we have been aware of the increasing possibility of radiation-related injuries since the early 1990s, when the issue was first raised by the U.S. Food and Drug Administration (FDA). SIR conducted the first detailed study of radiation doses in IR procedures in the late 1990s at the request of FDA—the RAD-IR study. (5,6) We shared the results of the RAD-IR study with FDA prior to publication and have been involved in measures to educate the public, our members, referring clinicians, and equipment manufacturers very actively both before and since then.

Only an appropriately credentialed physician has the skills, training, and experience to oversee the safe performance of fluoroscopy. It must be remembered that fluoroscopic procedures carry a risk of exposure to radiation, with related injuries (5, 6, 7). Patient radiation dose during fluoroscopy is dependent on the operator's training, experience with the

fluoroscope, and efficiency in completing the study. The influence of training on radiation times and exposures has been demonstrated in studies of complex fluoroscopically-guided procedures (8,9). Patients can be harmed as a result of these fluoroscopically-guided procedures, as demonstrated in multiple publications, including the FDA document by Shope (10). These injuries can occur even when fluoroscopy is used by well-trained persons; imagine the risk from use by those not well trained or not trained at all in radiation protection and radiation management. There can be substantial increases in radiation dose to the patient when the fluoroscopist does not use proper technique (11).

In addition to the patient, we must consider those receiving occupational exposure. Without proper training, and without the use of appropriate technique, the operator's occupational dose will be higher than necessary (12). For orthopedic and pain management procedures, this is particularly true for the operator's hands (13). SIR continues to advocate with industry, partner societies, and regulatory agencies for reduced operator dose, through training, standards, and board certification of our members. We have worked with our partner organizations representing technologists and nurses. We strongly believe that the use of any tool that carries risk should require demonstrated competency and adherence to standards by the user prior to its application.

Thank you for your consideration of our comments. If we can provide any additional information or if you have questions and would like to discuss our comments in more detail, please do not hesitate to contact me at bstainken@rwmc.org or (401) 456-2204, Tricia McClenny, Associate Executive Director, in the SIR office at tricia@SIRweb.org or (703) 691-1805, or Doug Huynh, Manager of Government Affairs, at dhuyh@SIRweb.org or (703) 691-1805.

Sincerely,



Brian Stainken, MD, FSIR
President, Society of Interventional Radiology

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February 19, 2010

**Society for Radiation Oncology Administrators Statement
on
Quality Radiation Therapy**

Submitted to Representative Sue Myrick, Member, Subcommittee on Health, Committee on Energy and Commerce, House of Representatives, Congress of the United States, for consideration at the Subcommittee Hearing on **"Medical Radiation: An Overview of the Issues."**

On behalf of the Society for Radiation Oncology Administrators (SROA), we thank you for allowing us to contribute to a dialogue on the quality of radiation therapy and its effect on our patients across the country.

You will hear from radiation therapists, radiation oncologists, medical physicists, administrators and others who are all essential members of a larger team treating millions of cancer patients. We understand the reason behind calling this hearing in light of the questions cancer patients and their families across the nation are asking these professionals following the *New York Times* articles on radiation overdoses. However, as the administrators who oversee the staff, quality assurance and patient safety of radiation oncology programs, we are here to reassure this body and the public that our efforts to ensure that patients receive the best and safest care possible are vigorous and ongoing.

To provide background, the Society for Radiation Oncology is the authority on radiation oncology operations. As such, we are committed to providing education, advocacy and information to radiation oncology administrators. Our 600 plus members work in all settings where radiation therapy is provided. SROA is guided by four objectives:

1. Improve the administration of the business and nonmedical management aspects of radiation oncology and the practice of radiation oncology as a cost-effective form of health care delivery.
2. Provide a forum for dialogue among the members on matters of professional interest.

The source for proactive solutions for cancer care delivery.

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3. Disseminate information to and among the members of the Society.
4. Generally promote the field of radiation oncology administration.

Unfortunately, the recent *New York Times* articles did not highlight the day-to-day efforts to and successes in providing safe, effective cancer treatments. You will hear from one of the accrediting bodies for radiation oncology, the American College of Radiology that currently accredits 213 radiation oncology centers in the United States. These centers have undergone a rigorous review process based on nationally accepted standards and guidelines that compare the facility's personnel, equipment, treatment planning and treatment records, along with its quality control measures.

To provide an idea of the number of staff that work diligently to provide patient safety in radiation therapy centers across the United States, in 2004 there were an estimated 29,970 individuals working in these facilities, according to RT Answers at www.rtanswers.com/statistics/aboutradiationtherapy.aspx. Those personnel included 3,900 radiation oncologists; 8,900 radiation therapists; 3,400 nurses; 2,600 radiation physicists; 2,500 dosimetrists; 5,300 clerical employees; 2,400 administrative staff and 900 other full-time employees.

As managers and administrators, we take responsibility for knowing national and state standards that apply to these practices. Because we have different backgrounds, we voluntarily seek additional education and use a team approach in applying quality assurance (QA). Our industry overall follows strict QA guidelines that establish a multilevel "check and balance" of preplanning, planning and treatment delivery processes for radiation therapy. We also have policies and procedures that define the steps to follow when a treatment deviates or an adverse event occurs. Our facilities must also meet and maintain national and state requirements for delivering radiation to patients. These statutes range from registering radiation-producing equipment to reporting a radiation medical event.

All these factors help ensure that patients who come to us for radiation therapy services are safe. We must earn the patient's trust. We also understand that patients who enter our facilities already may carry a load of fear along with pain and other symptoms related to the cancer. Therefore, our physicians and staff work hard to assure them and their families that the treatment they receive is applied at the highest possible standards and that we place patient safety above all else.

However, when the rare medical event happens, it is incumbent on the healthcare system as a whole to acknowledge and to learn from those mistakes immediately. We could use stronger regulatory bodies, such as state radiation control bureaus, that would hold physicians and staff responsible for reporting

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treatment deviation errors. Currently, many state regulations allow the radiation oncologist prescribing the treatment regimen to decide whether an error should be reported to the patient.

The National Academy for State Health Policy stated that only 21 states require some form of mandatory reporting of medical errors, according to the State-based Mandatory Reporting of Medical Errors: An Analysis of the Legal and Policy Issues at www.hashp.org/node/832. In turn, we need standard criteria on how to define the errors that can occur in our departments.

Most errors in radiation oncology are defined as treatment deviations. These are further defined as minor deviations because they can be corrected and insignificantly affect a patient's treatment outcome. However, the severity of a treatment deviation is user defined unless it falls under federal or state regulations that define a medical event such as but not limited to:

- The total dose delivered differs from the prescribed dose by 20 percent or more;
- The total dose delivered differs from the prescribed dose by 20 percent or more or falls outside the prescribed dose range; or the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
- Administration of a dose or dosage to the wrong individual or human research subject.
- Administration of a dose or dosage delivered by the wrong mode of treatment.

(Federal regulations, Subpart M—Reports § 35.3045 Report and notification of a medical event.)

Despite published reports, a large majority of radiation therapy departments have adopted a treatment deviation policy and a procedure to record, evaluate the cause of the deviation and establish corrective action to prevent future occurrences. However, we believe that it would be preferable to have a near-miss policy and procedure that documents the events leading to the discovery. Routine reporting of events and attention to near misses can help identify weak spots in this system and are particularly critical for reducing the risk of random errors but do not reduce risk of systematic errors.

As our processes become more and more complicated through technological advancements that seemingly automate much of the process, it is inherent that we maintain the human aspect of this care environment that monitors and guards against misadministrations.

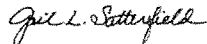
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As administrators, we also need adequate qualified staffing and reasonable workloads and funds to train staff on interpersonal skills, provide tools for patient education and communication, and monitor staff interactions. SROA has aligned with 22 other professional organizations to support the American Society of Radiologic Technologists (ASRT) in its efforts to achieve a national minimum education standard for those administering diagnostic or therapeutic radiation through the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) bill, H. R. 3652 bill. This effort began in 1999. We are frustrated and disappointed with a process that is costly and has brought us no closer to reality for our patients through the very education and certification that the *New York Times* article said we needed. Our industry needs the legislative and the executive branches to listen to our profession's experts so that stronger requirements can be passed to make the use of medical radiation safer for the public today and tomorrow

Finally, our membership would like to know why it takes reports of catastrophic events as the "lead story" on the 6 p.m. and 10 p.m. newscasts or the front page of one or more of our national newspapers to get the attention that this issue and our patients deserve. For decades, the radiation oncology professional organizations have worked together to make the use of medical radiation safe, where 99.996% of radiation treatments are correctly administered. However, that is not good enough, so we strive to reach 100%. Our patients and the public deserve that.

This brings us full circle to the most important aspect of every practice: the patient. With so many of our patients now questioning the safety of their radiation treatments, SROA is creating tools and looking to our fellow professional organizations' tools to provide our members with guidelines that they can use to assess their radiation oncology practices and improve patient education on radiation safety. We want to empower our patients and our profession in all the ways we have suggested in this statement.

Thank your for considering our comments. Please contact SROA if you have questions.



Gail L. Satterfield
President, SROA



R. Alan Burns, BS, R.T.(R)(T)
Chair, Advocacy Committee



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March 31, 2010

Rep. Edward Markey
House of Representatives
c/o Earley Green, Chief Clerk
2108 Rayburn House Office Building
Washington, DC 20515

Re: March 15, 2010 Letter from Chairman Waxman – “Medical Radiation – An Overview of the Issues”

Dear Representative Markey:

On behalf of the American Association of Physicists in Medicine (AAPM) attached are our responses to your follow-up questions from the Subcommittee on Health’s February 26th hearing titled “Medication Radiation: an Overview of the Issues.” AAPM represents more than 7,000 medical physicists and is committed to ensuring that all patients receive safe, high quality medical care.

If you have additional questions or require further information, please contact Lynne Fairbent, AAPM’s Manager of Legislative and Regulatory Affairs at lynne@aapm.org or 301-209-3364 or me.

Sincerely,

Michael G. Herman, Ph.D., FAAPM, FACMP

Cc: Committee on Energy and Commerce

1 Attachment



**The American Association of Physicists in Medicine's Response to
Questions from the Honorable Edward J. Markey
(Text in italics quoted from Rep. Markey's letter)**

Last summer an article in the New York Times¹ detailed a series of major medical mistakes that occurred at the Philadelphia Veterans Affairs Medical Center (VAMC) where a doctor retroactively altered treatment plans on procedures involving use of radioisotopes. In one particular case, the doctor incorrectly implanted radioactive iodine seeds into the patient's health healthy bladder, instead of into the patient's prostate gland where it was intended to treat his prostate cancer. These incidents raised many questions about the adequacy of the Nuclear Regulatory Commission, which has jurisdiction over these types of medical errors, to oversee and investigate these sorts of procedures.

1. *Do you think that if a physician accidentally irradiates the wrong body part during therapeutic treatment that this should be reported as an error, to the patient, the hospital and to regulatory authorities?*

Yes. It is the responsibility of the physician to inform the patient, the hospital authority and the regulatory agency.

2. *There are currently different reporting rules for different types of radiation-related errors that depend largely on what the source of radiation is. For example, errors related to irradiation with medical devices are reported to FDA, while the Nuclear Regulatory Commission (NRC) has authority over radiation exposure associated with radioactive materials. Do you think that if the wrong part of the body is irradiated that the rules for how this error is recorded and reported should be uniform despite the source of radiation?*

Yes. If the wrong part of the body is irradiated, the rules for how the error is recorded and reported should be uniform despite the source of radiation. From the impact of the radiation exposure, the risks and effects are the same for a similar dose of radiation, no matter what the source of the radiation was.

3. *Do you think that for oversight and research purposes it would be helpful to have data on medical errors, such as the one described above, collected by a centralized source? If yes, who do you think that source should be? If not, why not?*

Yes, data on medical errors is essential to conduct a trend analysis, make assessments, inform the community, and make improvements. We agree that there should be a centralized data repository of medical errors. Exactly how this is achieved should be discussed further. An independent source for the data collection such as the Conference

of Radiation Control Program Directors (CRCPD), that represents all state regulators could provide such a solution. A partnership between agencies, the medical community and organizations such as CRCPD could also effectively cooperate to develop this repository. The important requirements are that the system allows all of us to learn from actual and potential adverse events in the medical use of radiation by:

- allowing central reporting by medical staff (including radiation therapy physicians, medical physicists, radiation therapists, dosimetrists, others), manufacturers and others in a complete and consistent manner,
- providing search capability to identify patterns, risks and corrective actions and to inform the community, and
- require a partnership between all involved (federal and state government, manufacturers, users, patient advocates).

The national system must be set up in such a way as to be independent of any reporting entity to prevent bias in the data reported. The database should be established such that no patient identification is included in the reports submitted to the reporting entity. The AAPM has been in conversation with FDA to organize a national roundtable for exactly this discussion.

4. *What kind of information about the circumstances of a medical error should be reported and collected?*

The essential components of any database should include description of the event, the specific equipment, protocol, and procedure type, all in a HIPAA compliant manner. This is similar to the essential components required in the Nuclear Regulatory Commission's Nuclear Materials Event Database (NMED). The reporter should also include at least a preliminary analysis of the root causes of the event. Provisions should be made for anonymous reporting of events, which has been demonstrated to increase the frequency of reports.

5. *Currently, requirements on patient notification after a medical error such as irradiating the wrong organ, varies widely and depends again on the source of radiation. Under what circumstances do you think that patients should be notified of errors in their radiation procedure? Do you believe that rules about patient notification should be uniform across all States?*

Yes, except in rare cases where notification would cause more patient harm than help. Patients should be notified and the rules should be uniform across all states.

6. *How should medical error and mis-administrations be defined?*

AAPM believes that the definition of medical error should be uniform across radiation treatments. We also believe that the stakeholder community should have an opportunity to work with the regulatory authorities to establish the definition of a medical event that would be uniformly applied. It is possible that the definition of medical error may be

procedure specific, but should remain consistent across the country. There are various models (NRC, some states, FDA- and internationally IAEA) that exist, are different, but could serve as a beginning for developing a uniform system. Such definitions should be expanded to include events that do not cause harm to the patient, but have the potential to do so.

7. Do you think that there should be a standardized definition and mandatory reporting framework for machine-based radiation that is consistent in every State?

Yes, and this should follow our answers to items 3, 4, 5 and 6 above. There are several states (e.g., PA, NY, FL) that currently have definitions and mandatory reporting systems in place, but many that do not. A central and national system as described above should include these events.

8. Do you think that errors in administration should be consistently tracked by the States, independent of the source of radiation (i.e., for both machine-based and non-machine-based radiation)?

Yes. The impact of the radiation exposure, the risks and effects are the same for a similar dose, no matter what the source of the radiation was – whether radioactive materials or resulting from the operation of radiation-producing equipment.

In 1997, NRC changed its regulations (10 CFR 35.75) to allow the immediate release of most cancer patients being treated with medical radioisotopes. In some cases this allows patients who could be emitting unsafe levels of radiation to be released, potentially harming people who might come into contact with them. According to a letter sent from the Nuclear Regulatory Commission to Congressman Edward Markey, it changed these rules because it assumed that the treating physician would be able to perform an individualized analysis of a patient's living situation to ensure that they would not pose harm to their family or the public.

9. Some patients choose to go to hotels to recover rather than return home to their families. Is a physician capable of performing an individualized analysis of a hotel room that he or she has never seen to ensure that neither hotel personnel nor future room inhabitants would be exposed to unsafe levels of radiation?

The current regulation does not mandate but allows patient release after a determination is made that the patient can comply with appropriate restrictions. It is the responsibility of the licensee to determine if a patient can be released in accordance with 10 CFR § 35.75. Licensees who are authorized to release patients containing more than 33 mCi of radioactive iodine-131 are required to perform an analysis of the potential radiation exposure to others to assure regulatory limits are not exceeded. NUREG-1556, Volume 9 Section 8.36, *Release of Patients or Human Research Subjects* specifies the guidelines

AAPM Response to Rep. Markey's Questions
March 31, 2010
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that must be followed by a licensee prior to releasing a patient in accordance with 10 CFR § 35.75.

The assumptions that the licensee is required to make are conservative. We believe that the existing regulation provides adequate protection of the public. There are patients who may not be candidates for release but that determination should continue to be based on an assessment by the authorized medical professionals involved, and not solely dictated by a simplistic regulation based on a defined quantity of administered radioactivity.

It is imperative, however, that the patient answers questions truthfully and follows the written instructions. Licensees should not be held accountable for patients who choose to ignore the instructions and directions given prior to their release. This is no different than a patient who disregards the instructions on a prescription drug label or over the counter drug.

AAPM discourages the release of patients to hotels following treatment with radioactive iodine-131. While the actual risk to hotel staff might be very small, the public perception of such activity is quite negative and the practice may not reflect an adequate safety culture."

10. In this type of a release situation, how does a physician take into account exposure of hotel workers or future hotel guests who might come into contact with the radioactive sheets and other contamination that the patient leaves behind?

NUREG 1556, Volume 9, Appendix U: *Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials* lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR § 35.75. The activity at which patients could be released is calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, *Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides*.

Appendix U also discusses the instructions that must be given to the patient prior to the release. Many facilities require the patient to sign these instructions sheets acknowledging the conditions under which they are being released. As stated in response to Question 9 above, licensees should not be held accountable for patients that do not follow the instructions provided to them.

We note that the current dose limit of 5 mSv per treatment to others post-release of the patient assumes that they will be family members, caregivers or others with an interest in the patient, and who will have rare exposure in such situations. Hotel workers do not fall in this category and thus should be limited to 1 mSv per year. Such a prediction is generally beyond the ability of the licensee to make, thus the general process of release to a hotel should be prohibited.



March 26, 2010

Rep. Henry A. Waxman
Chairman
Committee on Energy and Commerce
House of Representatives
c/o Earley Green, Chief Clerk
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Waxman:

Thank you for the opportunity to respond to Rep. Edward Markey's follow-up questions from the Subcommittee on Health's Feb. 26 hearing titled "Medication Radiation: an Overview of the Issues." I was honored to be invited to testify on this important issue, and I appreciate being asked to provide additional information.

I am submitting the attached responses on behalf of the American Society of Radiologic Technologists, which represents more than 134,000 medical imaging and radiation therapy professionals. The ASRT is committed to ensuring that all patients receive safe, high quality radiologic care.

If you have additional questions or require further information, please contact me.

Sincerely,

A handwritten signature in cursive script that reads "Sandra E. Hayden".

Sandra Hayden, B.S., R.T.(T)
Vice Speaker of the ASRT House of Delegates
15000 Central Ave. SE
Albuquerque, NM 87123-3909
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Last summer an article in the New York Times¹ detailed a series of major medical mistakes that occurred at the Philadelphia Veterans Affairs Medical Center (VAMC) where a doctor retroactively altered treatment plans on procedures involving use of radioisotopes. In one particular case, the doctor incorrectly implanted radioactive iodine seeds into the patient's healthy bladder, instead of into the patient's prostate gland where it was intended to treat his prostate cancer. These incidents raised many questions about the adequacy of the Nuclear Regulatory Commission, which has jurisdiction over these types of medical errors, to oversee and investigate these sorts of procedures.

1. Do you think that if a physician accidentally irradiates the wrong body part during therapeutic treatment that this should be reported as an error, to the patient, the hospital and to regulatory authorities?

ASRT Response: The error at the Philadelphia VAMC involved brachytherapy (the internal placement of radioactive seed implants to treat cancer). External beam radiation therapy treatment is delivered by a radiation therapist based on prescriptive orders from a physician, development of a treatment plan by either a medical physicist or medical dosimetrist and treatment simulation by a radiation therapist. Ultimately it is the radiation therapist who delivers the radiation dose to the patient. The CARE Bill (H.R. 3652) will require all technical personnel performing medical imaging, along with radiation therapists, medical dosimetrists and medical physicists treating Medicare patients, to meet education and certification standards to help ensure treatments are conducted safely and effectively.

Misadministration of radiation dose should be reported if it results in an outcome that is different from what was originally intended. Reporting requirements should be based on severity:

- A minor misadministration of dose that has no clinical significance need only be reported to internal quality management bodies.
 - A misadministration of dose that affects the patient should be reported to the patient, his/her referring physician, the radiation oncologist supervising the patient's treatment, and external quality management bodies.
 - The supervising physician is responsible for reporting any misadministrations to the patient, while the radiation therapist or medical physicist is responsible for reporting any deviations to the facility.
 - The facility in which the treatment took place is responsible to state or federal regulatory authorities for any required reports.
 - For treatment using radioisotopes or radioactive seeds, the Nuclear Regulatory Commission has clear guidance and criteria on what constitutes a reportable event at 10 CFR 35.3045. FDA requires the manufacturer and the facility using radiation-emitting equipment to report any accidental radiation occurrences during the manufacture, testing or use of any product. Equipment operators and consumers may voluntarily report information to FDA.
2. There are currently different reporting rules for different types of radiation-related errors that depend largely on what the source of radiation is. For example, errors related to irradiation with medical devices are reported to FDA, while the Nuclear Regulatory Commission (NRC) has authority over radiation exposure associated with radioactive materials. Do you think that

if the wrong part of the body is irradiated that the rules for how this error is recorded and reported should be uniform despite the source of radiation?

ASRT Response: Each federal regulatory body's authority is determined by statute. Currently FDA is responsible for equipment that emits ionizing radiation (such as CT scanners or linear accelerators used in radiation therapy treatments) while NRC is responsible for radioactive materials (radioisotopes and radiation emitting seeds). Each agency should collect the same type of information using standardized definitions so that reporting is consistent and data can be compiled and analyzed to develop best practices for avoiding misadministrations or deviations from prescribed dose. Reporting requirements should be uniformly defined and applied.

3. Do you think that for oversight and research purposes it would be helpful to have data on medical errors, such as the one described above, collected by a centralized source? If yes, who do you think that source should be? If not, why not?

ASRT Response: Blinded data on medical radiation misadministrations should be collected, analyzed and available for research. Comprehensive data collections are vital to developing methods to prevent errors from occurring during treatment. FDA and NRC currently make radiation misadministration and equipment malfunction data available to the public. If this data was collected in a centralized source, the Agency for Healthcare Quality and Research may be the best repository.

4. What kind of information about the circumstances of a medical error should be reported and collected?

ASRT Response: All relevant data surrounding a medical error event should be collected. In the case of a radiation error, data should include the patient's condition for which the exam/treatment was prescribed, the prescribing physician, the supervising physician during the exam/treatment, patient demographic information, and the location, time and date where the event took place; the name/certifications/background of the operator performing the treatment or exam; the make and manufacturer of the equipment used, including software versions; technique and dose data for the exam/treatment; and any other information that is required by the agency to which the event is reported.

5. Currently, requirements on patient notification after a medical error such as irradiating the wrong organ, varies widely and depends again on the source of radiation. Under what circumstances do you think that patients should be notified of errors in their radiation procedure? Do you believe that rules about patient notification should be uniform across all States?

ASRT Response: Because the ordering and supervising physician(s) are responsible for patient notification, ASRT defers to their opinion and the position of their professional organizations. In general, the decision to notify the patient should be made by the head of the department of the patient's attending physician, after consulting with the attending physician and with the department's quality management organization.

6. Currently, reporting of medical errors or misadministrations involving radiation producing machines is regulated differently by individual States, with variability in both the reporting requirements and how a misadministration or medical event is defined. How should medical error and misadministrations be defined?

ASRT Response: ASRT recommends that nationally recognized medical research organizations (such as the Institutes of Medicine) be consulted to define the terms "medical error" or "misadministration." States also may have definitions of "misadministration" as parts of reporting policies. For example, Pennsylvania Code (25 Pa. Code § 219.3) defines a reportable event in radiation therapy as:

"Medical reportable event for radiation-producing machine therapy. The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

- (i) An administration of a therapeutic radiation dose to the wrong individual;
- (ii) An administration of a dose for therapy when the result is an increase in the total expected doses inside or outside the intended treatment volume for organs, tissue, or skin that exceeds 20% of the total prescribed dose for the intended target volume;
- (iii) A total dose delivered to the treatment site identified in a written directive for therapy that is outside the prescribed dose range or differs from the total prescribed dose by more than 20%, or for a fractionated dose, when the weekly administered dose differs from the weekly prescribed dose by more than 30%."

7. Do you think that there should be a standardized definition and mandatory reporting framework for machine-based radiation that is consistent in every State?

ASRT Response: ASRT believes that definitions and reporting requirements should be standardized and consistent in each state. By developing data collection requirements, research organizations and associations representing the professions involved in medical imaging and radiation therapy can develop best practices and evidence-based methods to reduce the potential of misadministrations and errors.

8. Do you think that errors in administration should be consistently tracked by the States, independent of the source of radiation (i.e. for both machine-based and nonmachine-based radiation)?

ASRT Response: Radiation administered by an educated and certified individual can be used to detect, diagnose and treat disease and illness. However, in the hands of an untrained operator, radiation has the potential to harm, or even kill, those who may benefit from its medical use. Any error or unintended consequence resulting from the misuse of radiation, regardless of the source (equipment emitting ionizing radiation or physical sources of radiation like radioisotopes or radiation emitting seeds) should be tracked and recorded.

In 1997, NRC changed its regulations (10 CFR 35.75) to allow the immediate release of most cancer patients being treated with medical radioisotopes. In some cases this allows patients who could be emitting unsafe levels of radiation to be released, potentially harming people who might come into contact with them. According to a letter sent from the Nuclear Regulatory Commission to Congressman Edward Markey, it changed these rules because it assumed that the treating physician would be able to perform an individualized analysis of a patient's living situation to ensure that they would not pose harm to their family or the public.

9. Some patients choose to go to hotels to recover rather than return home to their families. Is a physician capable of performing an individualized analysis of a hotel room that he or she has never seen to ensure that neither hotel personnel nor future room inhabitants would be exposed to unsafe levels of radiation?

ASRT Response: National, and general, guidelines should exist to protect members of the public. It should be the responsibility of the licensee to properly advise the patient of proper procedures to be followed in order to minimize unnecessary irradiation of family members or members of the public.

10. In this type of a release situation, how does a physician take into account exposure of hotel workers or future hotel guests who might come into contact with the radioactive sheets and other contamination that the patient leaves behind?

ASRT Response: Instructions provided to the patient should provide specific guidance such that the exposure of members of the public are maintained as low as reasonable achievable. It should be the responsibility of the licensee to show how this has been done.

March 31, 2010

Earley Green, Chief Clerk
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn HOB
Washington, DC 20515-6115

Via e-mail: Earley.Green@mail.house.gov

Dear Chief Clerk Green:

The following response is given in reply to Chairman Waxman's request dated March 15, 2010 as follow-up to the February 26, 2010 hearing entitled Medical Radiation, An Overview of Issues."

Sincerely,

E. Stephen Amis, Jr, MD, FACR
Albert Einstein College of Medicine/Montefiore Medical Center
Chair, ACR Blue Ribbon Panel on Radiation Dose in Medicine

Last summer an article in the New York Times detailed a series of major medical mistakes that occurred at the Philadelphia Veterans Affairs Medical Center (VAMC) where a doctor retroactively altered treatment plans on procedures involving use of radioisotopes. In one particular case, the doctor incorrectly implanted radioactive iodine seeds into the patient's health healthy bladder, instead of into the patient's prostate gland where it was intended to treat his prostate cancer. These incidents raised many questions about the adequacy of the Nuclear Regulatory Commission, which has jurisdiction over these types of medical errors, to oversee and investigate these sorts of procedures.

Question 1: Do you think that if a physician accidentally irradiates the wrong body part during therapeutic treatment that this should be reported as an error, to the patient, the hospital and to regulatory authorities?

Irradiation of a wrong body part during a therapy under the specific circumstances that occurred at the Philadelphia Veterans Affairs Medical Center (VAMC) should be reported. In that case, "medical event" reporting was required to patients, providers, and the appropriate authorities. 10 CFR Part 35.3045 regulates reporting and notification of medical events involving radioactive materials. These regulations address reporting to the patient/guardian, referring physicians,

and NRC within specific timeframes after discovery of the medical event. The VAMC was found to be in violation of the regulations and was penalized accordingly.

Error reporting is an “after the fact” approach that, by itself, is of questionable value. Resources for radiation therapy quality improvement and assessment would be better spent on monitoring medical facilities as part of a mandatory accreditation program to catch potential problem areas before errors occur. The VAMC exemplifies the limits of even the most stringent and punitive federal/State reporting requirements. It also emphasizes the importance of relying only on recognized accrediting bodies that offer a robust program carried out by experts in the modalities being accredited.

Question 2: There are currently different reporting rules for different types of radiation-related errors that depend largely on what the source of radiation is. For example, errors related to irradiation with medical devices are reported to FDA, while the Nuclear Regulatory Commission (NRC) has authority over radiation exposure associated with radioactive materials. Do you think that if the wrong part of the body is irradiated that the rules for how this error is recorded and reported should be uniform despite the source of radiation?

The goal for any medical error reporting system should be quality improvement. Generally, error reporting and quality improvement initiatives will be most effective at the facility level where the consequences of a medical error are most keenly felt and where the specific circumstances giving rise to an error can be most readily identified and remedied.

Speaking specifically to the question of uniformity, there are meaningful differences in medical errors involving various uses of radiation; a regulatory scheme that treats all errors as though they were identical would be counterproductive. For example, radioisotopes, which are subject to NRC reporting requirements, are used and administered differently, have different handling requirements, use different equipment, and have different quality assurance/quality control requirements than devices that use external radiation.

Before deciding whether to collect medical error data at the national level, a risk threshold should be developed in an open deliberative process, relying on the expertise of clinicians (physicians and medical physicists) who plan and perform the specific types of procedures being discussed. Errors that do not result in adverse outcomes should continue to be reported locally to the respective healthcare facility and, if feasible, de-identified summary statistics might also be included in a medical specialty data registry, such as the American College of Radiology’s General Radiology Improvement Database (GRID).

Furthermore, to ensure that the reported data is viewed in the appropriate context, there should be mechanisms to verify consistency in reporting among all providers. Repeat exams resulting from poor techniques, antiquated imaging equipment, inadequate clinical skills, etc. should also be reportable if the additional dose required by the repeat exam triggers the reporting threshold. Repeat examinations are more prevalent in certain ambulatory settings in which physicians without extensive training in radiology—including the radiation safety fundamentals taught in residency training of radiologists, radiation oncologists, and nuclear medicine physicians—are providing diagnostic imaging or radiation therapy services.

Question 3: Do you think that for oversight and research purposes it would be helpful to have data on medical errors, such as the one described above, collected by a centralized source? If yes, who do you think that source should be? If not, why not?

De-identified data on medical errors across medicine collected specifically for research purposes could potentially be useful depending on how the data is used. However, ACR believes the relative usefulness of data collection is low unless several additional steps are taken to translate the research into clinical practice at the facility level. If a decision to collect such data is made, it should be collected across all medical specialties without regard to the practice setting, device, procedure, specialty of the clinician, or whether the error involved radiation. We are hopeful that reporting of this data would be, in the near future, facilitated by health information technology and exchange capabilities.

In terms of where the data is retained, there may not be a need for a centralized archive/storage location for this data, as long as this data is accessible to those who need it. The Agency for Healthcare Research and Quality (AHRQ) has made some headway on a variety of topics related to medical errors data reporting and analysis.¹

Furthermore, defining what constitutes a medical error can be challenging as demonstrated by the deliberations of NRC's Advisory Committee on the Medical Uses of Isotopes on such topics. There are certainly occasions where most physicians would agree that an error was made, others where most would agree a mistake was not made, and still others where no consensus would be found. Schemes for mandatory reporting should be designed so as not to interfere with the appropriate practice of medicine with respect to the individualized needs and circumstances of the patients. The development of criteria for medical error reporting should be done in an open deliberative process, relying on the expertise of clinicians (physicians and medical physicists) who plan and perform the specific types of procedures being discussed.

Question 4: What kind of information about the circumstances of a medical error should be reported and collected?

The circumstances of a medical error that would be useful would undoubtedly vary by procedure. For this reason, ACR would strongly recommend that the development of criteria for medical error reporting should be done in an open deliberative process, relying on the expertise of clinicians who plan and perform the specific types of procedures being discussed.

Question 5: Currently, requirements on patient notification after a medical error such as irradiating the wrong organ, varies widely and depends again on the source of radiation. Under what circumstances do you think that patients should be notified of errors in their radiation procedure? Do you believe that rules about patient notification should be uniform across all States?

Ideally, patient notification requirements relating to medical errors should be consistent for all medical errors without regard to whether radiation was used and /or the source of the

¹ Agency for Healthcare Research and Quality (AHRQ), "Medical Errors & Patient Safety," <http://www.ahrq.gov/qual/errorsix.htm>.

radiation. Consideration should be given as to whether a patient was harmed or potentially harmed by the error, what information should be conveyed and how it can be conveyed so as to urge any appropriate follow-up but not cause undue worry, etc.

The NRC currently has regulations in 10 CFR Part 35.3045 that address the reporting and notification of “medical events” including, but not limited to, errors and misadministrations involving radioactive materials. Medical events are not necessarily “preventable adverse events;” that is, they do not always result in harm to patients. As a result, NRC’s reporting requirements can sometimes cause patients, and referring physicians who are not familiar with NRC medical event reporting requirements, undue confusion and anxiety.

Many States have malpractice protections in place to facilitate reporting of medical errors—disclosure protections are strongly encouraged for medical errors that do not result in adverse events.

Currently, reporting of medical errors or mis-administrations involving radiation producing machines is regulated differently by individual States, with variability in both the reporting requirements and how a mis-administration or medical event is defined.

Question 6: How should medical error and mis-administrations be defined?

The Institute of Medicine (IOM) defines a medical “error” as the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim. A “misadministration” in nuclear medicine services is related to incorrect procedure, dose, route of administration, or target area—this term is also used across medical disciplines in general reference to medication administration errors.

As noted above, ACR would strongly recommend that the development of criteria for medical error reporting should be done in an open deliberative process, relying on the expertise of clinicians who perform the specific types of procedures being discussed.

Question 7: Do you think that there should be a standardized definition and mandatory reporting framework for machine-based radiation that is consistent in every State?

Standardization would facilitate cross-state analysis of reporting data. Not knowing what the standardized definition or reporting framework might be, it is impossible to comment on whether a universal application of the framework or definition would be helpful or harmful.

Question 8: Do you think that errors in administration should be consistently tracked by the States, independent of the source of radiation (ie. for both machine-based and nonmachine-based radiation)?

Consistent tracking of medical errors by the appropriate federal/State authorities could facilitate analysis of errors that could potentially foster quality improvement efforts. The definition of medical error and the types of information that might be useful to collect could vary based on the type of procedure, the characteristics of the body part treated, the device or material used,

the degree to which a procedure requires an exercise of medical judgment in carrying out a procedure, etc.

ACR would strongly recommend that the development of criteria for medical errors should be done in an open deliberative process, relying on the expertise of clinicians who plan and perform the specific types of procedures being discussed.

In 1997, NRC changed its regulations (10 CFR 35.75) to allow the immediate release of most cancer patients being treated with medical radioisotopes. In some cases this allows patients who could be emitting unsafe levels of radiation to be released, potentially harming people who might come into contact with them. According to a letter sent from the Nuclear Regulatory Commission to Congressman Edward Markey, it changed these rules because it assumed that the treating physician would be able to perform an individualized analysis of a patient's living situation to ensure that they would not pose harm to their family or the public.

Question 9: Some patients choose to go to hotels to recover rather than return home to their families. Is a physician capable of performing an individualized analysis of a hotel room that he or she has never seen to ensure that neither hotel personnel nor future room inhabitants would be exposed to unsafe levels of radiation?

Physicians can make the determination to hospitalize or release patients administered radioisotopes in accordance with 10 CFR Part 35.75. NRC also provides regulatory guidance in Appendix U of NUREG 1556, Volume 9, Revision 2 and in Regulatory Issue Summary (RIS) 2008-11. Additionally, several medical and scientific organizations provide guidelines and standards that address aspects of I-131 therapy in general, including patient release.

A physician who decides to hospitalize or release a patient following I-131 therapy makes reasonable assumptions and conservative calculations, in accordance with modern scientific methodologies, regarding radiation exposure risk to the public. Physicians and/or medical physicists and health physicists can make safe, conservative assessments of public exposure risk without reviewing floor plans, as the major method for estimating exposure risk conservatively assumes a hypothetical person would consistently be within 1 meter of the patient. Since 1997, when 10 CFR Part 35.75 was updated to be in accordance with modern scientific methodologies, there have been no known physical harms resulting from public exposure to appropriately released I-131 patients.

Question 10: In this type of a release situation, how does a physician take into account exposure of hotel workers or future hotel guests who might come into contact with the radioactive sheets and other contamination that the patient leaves behind?

For all patient release scenarios, licensees must determine that the total effective dose equivalent to any other individual from exposure to the patient is not likely to exceed 5 mSv in accordance with 10 CFR Part 35.75. As mentioned in the previous answer, medical personnel have various scientific methodologies that facilitate this determination. Studies show that the

resultant radiation exposure to those around appropriately released I-131 patients is well below safe ICRP/NCRP recommended and NRC-mandated levels.^{2,3}

² Grigsby PW, Siegel BA, Baker S, Eichling JO. Radiation exposure from outpatient radioactive iodine (¹³¹I) therapy for thyroid carcinoma. JAMA. 2000 May 3;283(17):2272-4.

³ Venencia, C. D., Germanier, A. G., Bustos, S. R., Giovannini, A. A., and Wyse, E. P. Hospital discharge of patients with thyroid carcinoma treated with ¹³¹I. J.Nucl.Med., 43: 61-65, 2002.

Questions for the Record
The Honorable Henry Waxman
Chairman
House Committee on Energy and Commerce
Subcommittee on Health
“Medical Radiation: An Overview of the Issues”
February 26, 2010

Question 1: Do you think that if a physician accidentally irradiates the wrong body part during therapeutic treatment that this should be reported as an error, to the patient, the hospital and to regulatory authorities?

Response: Yes. These disclosures should not be limited to wrong body part. Depending on specific circumstances, the administration of any wrong treatment (such as overdosing, underdosing, or misaligned exposures from therapeutic radiation) or the occurrence of an adverse event should be disclosed to the patient and the hospital's quality management and patient safety offices.

Veterans Health Administration (VHA) facilities and individual VHA providers have an ethical and legal obligation to disclose to patients adverse events that have been sustained in the course of their care, including cases where the adverse event may not be obvious or severe, or where the harm may only be evident in the future. An adverse event (AE) is any unanticipated occurrence that ultimately results in harm to the patient.

Disclosure of AEs and the reporting of adverse events to regulatory agencies are separate requirements. Actions taken to disclose adverse events to patients according to VHA Directive 2008-002 “Disclosure of Adverse Events to Patients” in no way obviates the need to report adverse events (and close calls) as required under VHA Handbook 1050.01. Clinical disclosure of an adverse event must occur within 24 hours of a practitioner's discovery of the event. Other adverse events, such as unanticipated toxicity of treatment, must be disclosed within 24 hours upon information made available to the practitioner.

Treatment of the wrong patient, wrong organ or with the wrong isotope must be reported as a medical event in certain conditions per 10 CFR part 35 (the Nuclear Regulatory Commission's regulations on Medical Use of Byproduct Material) when that treatment involves the use of byproduct material. A medical event is a specific term related to the inappropriate medical use of certain radioactive materials. Specific indications of inappropriate use are defined in 10 CFR part 35.3045. Generally, indications include the following: administration of the wrong radioisotope, wrong route of administration, administration to the wrong patient and administration of the wrong dose.

These regulations also require reporting when the correct site is treated but the dose over that course of treatment deviates by 20 percent from the planned dose. These

reports require notification of the patient, the referring physician, the Nuclear Regulatory Commission (NRC) and within VHA, notification of the National Health Physics Program (NHPP). VHA, through its NHPP, has reported to the NRC each medical event discovered at VA medical centers, whether a medical event was discovered by the medical center staff or the NHPP inspectors. The Philadelphia VA Medical Center was cited by both the NHPP and by the NRC for not recognizing medical events at an earlier date.

Question 2: There are currently different reporting rules for different types of radiation-related errors that depend largely on what the source of radiation is. For example, errors related to irradiation with medical devices are reported to FDA, while the NRC has authority over radiation exposure associated with radioactive materials. Do you think that if the wrong part of the body is irradiated that the rules for how this error is recorded and reported should be uniform despite the source of radiation?

Response: Yes. Both a uniform set of definitions of radiation delivery errors and uniform requirements for their reporting should be requirements for licensing and accreditation of each radiation treatment facility. Note that for medical devices that incorporate or use radioactive materials, both FDA and NRC adverse event reporting rules will apply, depending on whether the reporting criteria are met.

Reporting of medical errors involving radioactive materials falls under both the FDA and the NRC for VHA. Reporting of certain patient injuries and medical errors related to the use of radiation-emitting medical devices are required by the Food and Drug Administration (FDA), as the FDA regulates the manufacturers of medical devices and electronic products that emit radiation. Likewise, reporting of medical misadministration is required by the NRC, as the NRC regulates facilities that produce and use radioactive materials for medical purposes. While both FDA and NRC have established process for communicating safety issues, there is value in improving uniformity of reporting criteria and rules.

In addition, medical physics oversight for quality assurance should be a requirement for licensure and accreditation. While several persons testifying at the hearing introduced the current Medical Physics Quality Assurance (QA) Program run by the National Cancer Institute (NCI), which provides routine surveys of VHA radiation oncology services, this program supports a limited number of radiation oncology practices. A national medical physics QA program offering this level of assurance to every radiation oncology practice would require a much larger effort.

Defining medical treatment errors related to radiation therapy is a complex task. Each of the professional agencies: the American Association of Physicists in Medicine (AAPM), the American College of Radiology (ACR), and the American Society for Radiation Oncology (ASRO) has committees or task groups that address radiation safety. As a result of the *New York Times* articles, these three organizations have formed a Joint Safety Task Force, which could address this very important need. The VA supports this important effort.

Question 3: Do you think that for oversight and research purposes it would be helpful to have data on medical errors, such as the one described above, collected by a centralized source? If yes, who do you think that source should be? If not, why not?

Response: Yes, VA supports the concept of having a centralized source for data on medical errors. One way to achieve this could be to have the Federal Government recreate regional Centers for Radiologic Physics (CRP) that would operate radiation therapy quality assurance programs. Data related to medical errors could then be tracked nationally, providing a larger database.

These centers fell into disuse more than 20 years ago, although the Radiologic Physics Center still exists and operates the National Cancer Institute's medical physics quality assurance program. The centers were funded by user fees, but their use was not mandatory.

Other alternatives might also be viable. For example, HHS's Agency for Healthcare Research and Quality currently lists Patient Safety Organizations (PSOs) with whom health care providers can voluntarily contract to collect, aggregate, and analyze adverse event reports. Eventually, all adverse event data collected by PSOs nationwide is expected to be connected through a Network of Patient Safety Databases. VA has not engaged in discussions with the Nuclear Regulatory Commission or other organizations on this subject.

Question 4: What kind of information about the circumstances of a medical error should be reported and collected?

Response: The appropriate medical and medical physics data will include an anatomical description of the treated volume, a description of collaterally irradiated tissues, a description of the 3D volumetric dose distribution including the dose volume histograms, medical equipment and/or radioactive sources involved in the event, as well as those dosimetric parameters required to characterize the exposure. The specific data will depend on the nature of the irradiation source, delivery mode and exposed volume. This level of detail should be provided by the relevant professional organizations, such as the Joint Safety Task Force introduced in the response to question 2. In addition, FDA's Medical Device Reporting regulations at 21 CFR part 803 require user facilities to report certain data relating to individual adverse event reports. It is important to note that reporting of data relating a medical error will require not only notification of the patient, but their referring physician and appropriate regulatory authorities.

Question 5: Currently, requirements on patient notification after a medical error such as irradiating the wrong organ, varies widely and depends again on the source of radiation. Under what circumstances do you think that patients should be notified of errors in their radiation procedure? Do you believe that rules about patient notification should be uniform across all States? Currently, reporting of medical errors or mis-administrations involving radiation producing machines is regulated differently by

individual States, with variability in both the reporting requirements and how a mis-administration or medical event is defined.

Response: While the specifics of this response should be provided by a consensus panel of experts from the appropriate professional societies, the general indications for patient notification are clear. These include any error in treatment which has the potential to cause injury, regardless of the inclusion of this level of injury in the informed consent process.

Rules related to the notification of patients due to an error in the delivery of medical radiation should not differ among individual states and Federal agencies. This uniformity should also apply to the definition(s) of medical radiation errors.

Question 6: How should medical error and mis-administrations be defined?

Response: Medical errors and mis-administrations of ionizing radiation produced by machine sources should be defined based upon the anatomy of the intended target volume and absorbed dose. Medical events for administrations involving radioactive materials are already defined, at the Federal level, in 10 CFR part 35. The accurate definition of a medical error involving machine sources will be complex, relating both to the dose delivered and to anatomic and/or geometric deviations from the planned treatment. Due to differences in the inherent accuracies of various forms of radiation treatment, there must be corresponding differences in which deviations constitute unacceptable errors.

Question 7: Do you think that there should be a standardized definition and mandatory reporting framework for machine-based radiation that is consistent in every State?

Response: Yes. As stated in the response to Question 2, above, uniformity of definitions and standardization of terminology are critically important. The most effective way to ensure this consistency is for a Federal entity to have responsibility, as suggested in the response to Question 3.

Question 8: Do you think errors in administration should be consistently tracked by the States, independent of the source of radiation (i.e. for both machine-based and non-machine-based radiation)?

Response: Data related to medical errors should be tracked nationally, providing a larger database. The larger database would have the potential to identify early emerging trends in radiation errors. See the responses to questions 2 and 3 for additional information.

Question 9: Some patients choose to go to hotels to recover rather than return home to their families. Is a physician capable of performing an individualized analysis of a hotel room that he or she has never seen to ensure that neither hotel personnel nor future room inhabitants would be exposed to unsafe levels of radiation?

Response: Yes, the physician authorized user is fully capable of evaluating patient circumstances in conjunction with the facility Radiation Safety Officer to make a determination about patient release. The NRC does not restrict the release of a patient to a hotel and has issued regulatory guidelines specific to this issue. These guidelines are in NUREG – 1556, Volume 9, Revision 2. A copy of this guidance is included as an attachment.

Question 10: In this type of a release situation, how does a physician take into account exposure of hotel workers or future hotel guests who might come into contact with the radioactive sheets and other contamination that the patient leaves behind?

Response: The NRC, through title 10, Code of Federal Regulations, Section 35.75 (b) restricts the release from confinement of any patient having received by-product material or certain cyclotron produced materials. Restrictions are based upon exposure levels determined by the physician in conjunction with the radiation safety officer. NUREG1556v9_rev2 Appendix U provides guidelines associated with those materials used in medical procedures.

Patients are classified into the following three groups: those whose release is unacceptable; those who once released have no limitation; and those who require special instructions regarding potential exposures to any other individual.

Examples of these instructions, deemed appropriate by NRC, are provided in the NUREG1556 cited above. For example, Appendix U Section 2.3.2 provides instructions for patients receiving a radioactive implant. The physician must, however, assess individual patient's capacity to follow these instructions. Once the physician and radiation safety officer have determined that a patient to be released meets those criteria requiring special instructions, those instructions are a mandatory condition of the release.

Attachment

APPENDIX U

**Model Procedure for Release of Patients or Human
Research Subjects Administered Radioactive
Materials**

Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the procedures for releasing patients administered radioactive materials also apply to the medical administration of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," of 10 CFR Part 35, "Medical Use of Byproduct Material," permits a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)." *Note:* As a result of the EPAct, byproduct material now includes accelerator-produced radioactive materials and discrete sources of radium-226.

In this Appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient."

Release Equation

The activity at which patients could be released was calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides." This report uses the following equation to calculate the exposure until time t at a distance r from the patient:

Equation U.1:

$$D(t) = \frac{34.6 \Gamma Q_0 T_p (1 - e^{-0.693t/T_p})}{r^2}$$

where: $D(t)$ = Accumulated exposure at time t , in roentgens
 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)
 Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm
 Q_0 = Initial activity of the point source in millicuries, at the time of the release
 T_p = Physical half-life in days
 r = Distance from the point source to the point of interest, in centimeters
 t = Exposure time in days.

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This Appendix uses the NCRP equation (Equation U.1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1 - e^{-0.693t/T_p})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).
- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Supplement A of Table U.5 in this Appendix.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation U.1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation U.2), at a distance of 1 meter. Selection of 25% of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicate the dose calculated using an occupancy factor, E , of 25% at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

Equation U.2:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (0.25)}{(100 \text{ cm})^2}$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor of 1.0 is used:

Equation U.3:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (1)}{(100 \text{ cm})^2}$$

Equations U.2 and U.3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent), relative to the external gamma dose (see "Internal Dose," of Supplement B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Item U.1.1, "Release of Patients Based on Administered Activity."

U.1 Release Criteria

Licensees should use one of the following options to release a patient to whom unsealed byproduct material or implants containing byproduct material have been administered in accordance with regulatory requirements. As a result of the EPAct, the unsealed byproduct material or implants now include accelerator-produced radioactive materials or discrete sources of radium-226.

U.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table U.1. The activities in Table U.1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using the following conservative assumptions:

- Administered activity;
- Physical half-life;
- Occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day and, to be conservative, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day; and
- No shielding by tissue.

The total effective dose equivalent is approximately equal to the external dose because the internal dose is a small fraction of the external dose (see Section B.3, "Internal Dose," of Supplement B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child, as discussed in Item U.3.2, "Records of Instructions for Breast-Feeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.40 and 35.63.

If the activity administered exceeds the activity in Column 1 of Table U.1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table U.1. In this case, 10 CFR 35.75(c) requires a record because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table U.1 were calculated using either Equation U.2 or U.3, depending on the physical half-life of the radionuclide.

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If a radionuclide that is not listed in Table U.1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, a calculation of the release activity that corresponds to the dose limit of 5 millisievert (0.5 rem). Equation U.2 or U.3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table U.1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in the patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table U.1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Items U.2.2 and U.2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d).

U.1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table U.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table U.1 for that radionuclide. In this case, however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table U.1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisieverts (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 10 CFR 35.75(c). The dose rate at 1 meter may be calculated from Equation U.2 or U.3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q / 10,000 \text{ cm}^2$.

U.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 millisievert (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table U.1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by 10 CFR 35.75(c). If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c).

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table U.1 Activities and Dose Rates for Authorizing Patient Release[†]				
Radionuclide	COLUMN 1 Activity At or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, At or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

Footnotes for Table U-1

- [†] The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.
- * If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c), because the measurement includes shielding by tissue. See Item U.3.1, "Records of Release," for information on records.

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** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The millicurie values were calculated using Equations U.2 or U.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicurie to gigabecquerels. The dose rate values are calculated using the millicurie values and the exposure rate constants.

In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

U.2 Instructions

This Section provides acceptable instructions for release of patients administered radioactive materials. Licensees may either adopt these model instructions or develop their own instructions to meet the requirements of 10 CFR 35.75.

U.2.1 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals ALARA after the patients are released.¹ Column 1 of Table U.2 provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. The activities or dose rates in Table U.2 may be used for determining when instructions must be given. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Item U.2.2, "Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release").

When patient-specific calculations (as described in Supplement B) are used, instructions must be provided if the calculation indicates a dose greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table U.2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation U.2 or U.3, as appropriate, may be used.

U.2.2 Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.¹ The purpose of the instructions (e.g., on interruption or discontinuation) is

¹NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.

to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if a radiopharmaceutical with an activity above the value stated in Column 1 of Table U.3 was administered to the patient, the licensee must give the patient instructions on the discontinuation or interruption period for breast-feeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table U.3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table U.3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table U.3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50% of the administered activity is excreted in the breast milk. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin (see Reference).

U.2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to U.2.3.1 and U.2.3.2).

Radionuclide	COLUMN 1		COLUMN 2	
	Activity Above Which Instructions Are Required		Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5

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Table U.2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release* (continued)				
Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

Footnotes for Table U.2

* The activity values were computed based on 1 millisievert (0.1 rem) total effective dose equivalent.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The values for activity were calculated using Equations U.2 or U.3 and the physical half-life. The values given in SI units (gigabecquerel values) were using conversion factors.

In general, values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

Table U.3 Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breast-Feeding an Infant or Child					
Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding
	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hours for 370 MBq (10 mCi) 12 hours for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.3	60	1.5	
Tc-99m DTPA	1000	30	6000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hours for 150 MBq (4 mCi)
Tc-99m Pertechnetate	100	3	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Tc-99m DISIDA	1000	30	6000	150	
Tc-99m Glucoheptonate	1000	30	6000	170	
Tc-99m MIBI	1000	30	6000	150	
Tc-99m MDP	1000	30	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell <i>In Vivo</i> Labeling	400	10	2000	50	6 hours for 740 MBq (20 mCi)
Tc-99m Red Blood Cell <i>In Vitro</i> Labeling	1000	30	6000	150	

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Table U.3 Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breast-Feeding an Infant or Child (continued)					
Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding
	(MBq)	(mCi)	(MBq)	(mCi)	
Tc-99m Sulfur Colloid	300	7	1000	35	6 hours for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1000	30	6000	150	
Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Ga-67 Citrate	1	0.04	7	0.2	1 month for 150 MBq (4 mCi) 2 weeks for 50 MBq (1.3 mCi) 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride	40	1	200	5	2 weeks for 110 MBq (3 mCi)

Footnotes for Table U.3

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

Notes: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material."

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding.

Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

U.2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine. This pamphlet was prepared jointly by the Society of Nuclear Medicine and the NRC. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. Although this pamphlet was written for the release of patients to whom less than 1,110 megabecquerels (30 millicuries) of iodine-131 had been administered, the NRC still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 10 CFR 35.75(b), provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 10 CFR 35.75(b)(1) and (2).

The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breast-feeding an infant or child is not in any way intended to interfere with the discretion and judgment of the physician in providing detailed instructions and recommendations.

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U.2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for _____ days.

- Stay at a distance of _____ feet from _____.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If you find a seed or pellet that falls out:
 - Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
 - Place the container with the seed or pellet in a location away from people.
 - Notify _____ at telephone number _____.

U.3 Records**U.3.1 Records of Release**

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table U.1; however, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information:

- **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this Appendix) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

- **For Immediate Release of a Patient Based on Measured Dose Rate:** The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.
- **For Delayed Release of a Patient Based on Radioactive Decay Calculation:** The time of the administration, the date and time of release, and the results of the decay calculation.
- **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by 10 CFR 35.75(c), should be kept in a manner that ensures the patient's confidentiality; that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

U.3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d). Column 2 of Table U.3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

U.4 Summary Table

Table U.4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

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Table U.4 Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained				
Patient Group	Basis for Release	Criteria for Release	Instructions Needed?	Release Records Required?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity \leq Column 1 of Table U.1	Yes – if administered activity $>$ Column 1 of Table U.2	No
	Retained activity	Retained activity \leq Column 1 of Table U.1	Yes – if retained activity $>$ Column 1 of Table U.2	Yes
	Measured dose rate	Measured dose rate \leq Column 2 of Table U.1	Yes – if dose rate $>$ Column 2 of Table U.2	Yes
	Patient-specific calculations	Calculated dose \leq 5 mSv (0.5 rem)	Yes – if calculated dose $>$ 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All the above bases for release		Additional instructions required if: Administered activity $>$ Column 1 of Table U.3 or Licensee calculated dose from breast-feeding $>$ 1 mSv (0.1 rem) to the infant or child	Records that instructions were provided are required if: Administered activity $>$ Column 2 of Table U.3 or Licensee calculated dose from continued breast-feeding $>$ 5 mSv (0.5 rem) to the infant or child

Implementation

The purpose of this section is to provide information to licensees and applicants regarding NRC staff's plans for using this Appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with 10 CFR 35.75, the methods described in this Appendix will be used in the evaluation of a licensee's compliance with 10 CFR 35.75.

Supplement A

Table U.5 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine		
Radionuclide	Physical Half-Life (days)¹	Exposure Rate Constant² (R/mCi-h at 1 cm)
Ag-111	7.45	0.15
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant ³	60.14	1.114
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant ³	74.02	4.594
P-32	14.29	N/A ⁵
Pd-103 implant ⁴	16.96	0.865
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2
Sn-117m	13.61	1.48
Sr-89	50.5	N/A ⁵
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Yb-169	32.01	1.83
Y-90	2.67	N/A ⁵
Yb-169	32.01	1.83

Footnotes for Table U.5

¹ K. F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

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- ² Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, p. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D. E. Barber, J. W. Baum, and C. B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, February 1997.
- ³ R. Nath, A. S. Meigooni, and J. A. Meli, "Dosimetry on Transverse Axes of ¹²⁵I and ¹⁹²Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.
- ⁴ A. S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.
- ⁵ Not applicable (N/A) because the release activity is not based on beta emissions.

References

- National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095.)
- S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Final Report), NRC, February 1997.
- M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," in *Pediatric Nuclear Medicine*, edited by S. Treves, Springer Verlag, New York, 1995.
- "Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

Supplement B

Procedures for Calculating Doses Based on Patient-Specific Factors

A licensee may release a patient to whom an activity with a value higher than the values listed in Column 1 of Table U.1 of this supplement has been administered if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential total effective dose equivalent to any individual would be no greater than 5 millisieverts (0.5 rem).

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, biological or effective half-life, or shielding by tissue, a record of the basis of the release is required by 10 CFR 35.75(c). The following equation can be used to calculate doses:

Equation B-1:

$$D(t) = \frac{34.6 \Gamma Q_0 TE (1 - e^{-0.693t/T_p})}{r^2}$$

- where: D(t) = Accumulated dose to time t, in rem;
 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44);
 Γ = Exposure rate constant for a point source, R/mCi x hr at 1 cm;
 Q_0 = Initial activity at the start of the time interval;
 T_p = Physical half-life, in days;
 E = Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient;
 r = Distance in centimeters. This value is typically 100 cm; and
 t = Exposure time in days.

B.1 Occupancy Factor

B.1.1 Rationale for Occupancy Factors Used to Derive Table U.1

In Table U.1 in this Appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members, as well as considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)), suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

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An occupancy factor of 0.25 at 1 meter may not be appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time. Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days; however, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table U.1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day. If information about a particular patient implies the assumptions were too conservative, licensees may consider case-specific conditions. Conversely, if young children are present in the household of the patient who is to be discharged, conservative assumptions about occupancy may be appropriate.

B.1.2 Occupancy Factors to Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, E , at 1 meter, may be useful for patient-specific calculations:

- $E = 0.75$ when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- $E = 0.25$ when an effective half-life is greater than 1 day, if the patient has been given instructions, such as:
 - Maintain a prudent distance from others for at least the first 2 days;
 - Sleep alone in a room for at least the first night;
 - Do not travel by airplane or mass transportation for at least the first day;
 - Do not travel on a prolonged automobile trip with others for at least the first 2 days;
 - Have sole use of a bathroom for at least the first 2 days; and
 - Drink plenty of fluids for at least the first 2 days.
- $E = 0.125$ when an effective half-life is greater than 1 day if the patient has been given instructions, such as:
 - Follow the instructions for $E = 0.25$ above;
 - Live alone for at least the first 2 days; and
 - Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of iodine-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to 1 day but is greater than 1 day for the other component, it is more

justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (60 millicuries) of iodine-131. The patient received instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay ($t = \infty$) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p E}{r^2}$$

Because the patient has received instructions for reducing exposure as recommended for an occupancy factor of $E = 0.125$, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6 (2.2 \text{ R} \cdot \text{cm}^2/\text{mCi}\cdot\text{hr})(60\text{mCi})(8.04 \text{ d})(0.125)}{(100 \text{ cm})^2}$$

$$D(\infty) = 4.59 \text{ millisieverts (0.459 rem)}$$

Since the dose is less than 5 millisievert (0.5 rem), the patient may be released, but 10 CFR 35.75(b) requires that instructions be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained, pursuant to 10 CFR 35.75(c), because an occupancy factor of less than 0.25 at 1 meter was used.

B.2 Effective Half-Life

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 10 CFR 35.75. The effective half-life is defined as:

Equation B-2:

$$T_{eff} = \frac{T_b \times T_p}{T_b + T_p}$$

where: T_b = Biological half-life of the radionuclide and
 T_p = Physical half-life of the radionuclide.

The behavior of iodine-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The

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effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2 , respectively) can be calculated with the following equations.

Equation B-3:

$$T_{1eff} = \frac{T_{b1} \times T_P}{T_{b1} + T_P}$$

Equation B-4:

$$T_{2eff} = \frac{T_{b2} \times T_P}{T_{b2} + T_P}$$

where: T_{b1} = Biological half-life for extrathyroidal iodide;
 T_{b2} = Biological half-life of iodide following uptake by the thyroid; and
 T_P = Physical half-life of iodine-131.

However, simple exponential excretion models do not account for: (a) the time for the iodine-131 to be absorbed from the stomach to the blood; and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of iodine-131.

Thus, an equation to calculate the dose from a patient administered iodine-131 may have three components. First is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B-1, using the physical half-life and a factor of 80%. Second is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at $t = 8$ hours based on the physical half-life of iodine-131. The second exponential factor represents the activity from $t = 8$ hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

Equation B-5:

$$D(\infty) = \frac{34.6 \Gamma Q_0}{(100 \text{ cm})^2} \left\{ E_1 T_P (0.8) (1 - e^{-0.693(0.33)/T_P}) \right. \\ \left. + e^{-0.693(0.33)/T_P} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/T_P} E_2 F_2 T_{2eff} \right\}$$

where: F_1 = Extrathyroidal uptake fraction;
 F_2 = Thyroidal uptake fraction;
 E_1 = Occupancy factor for the first 8 hours; and
 E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1 , $T_{1\text{eff}}$, F_2 , and $T_{2\text{eff}}$ are shown in Table U.6 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release required by 10 CFR 35.75(c) is described in Item U.3.1 of this Appendix.

Example 2, Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient to whom 5550 megabecquerels (150 millicuries) of iodine-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, the dose will be calculated by using Equation B-5 to account for the elimination of iodine-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table U.5. The uptake fractions and effective half-lives are from Table U.6. An occupancy factor, E , of 0.75 at 1 meter, will be used for the first component because the time period under consideration is less than 1 day; however, for the second and third components, an occupancy factor of 0.25 will be used, because: (1) the effective half-life associated with the dominant component is greater than 1 day; and (2) patient-specific questions were provided to the patient to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations," of this Supplement).

Medical Condition	Extrathyroidal Component		Thyroidal Component	
	Uptake Fraction F_1	Effective Half-Life $T_{1\text{eff}}$ (day)	Uptake Fraction F_2	Effective Half-Life $T_{2\text{eff}}$ (day)
Hyperthyroidism	0.20 ¹	0.32 ²	0.80 ¹	5.2 ¹
Post-Thyroidectomy for Thyroid Cancer	0.95 ³	0.32 ²	0.05 ³	7.3 ²

Footnotes for Table U.6

- ¹ M. G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75% of the data points shown in Figure 1 of the *Journal of Nuclear Medicine* document.
- ² International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in that document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer

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patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid), as suggested in the ICRP document.

³ The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC Medical Visiting Fellow, as an upper-limit post-thyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{(34.6) (2.2) (150)}{(100 \text{ cm})^2} \{ (0.75) (8.04) (0.8) (1 - e^{-0.693 (0.33) / 8.04}) \\ + e^{-0.693 (0.33) / 8.04} (0.25) (0.95) (0.32) \\ + e^{-0.693 (0.33) / 8.04} (0.25) (0.05) (7.3) \}$$

$$D(\infty) = 3.40 \text{ mSv (0.340 rem)}$$

Therefore, thyroid cancer patients to whom 5550 megabecquerels (150 millicuries) of iodine-131 or less have been administered would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose is not greater than 5 millisieverts (0.5 rem).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient to whom 2035 megabecquerels (55 millicuries) of iodine-131 have been administered for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, the dose will again be calculated using Equation B-5, Table U.5, and Table U.6, to account for the elimination of iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E , of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations").

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{(34.6) (2.2) (55)}{(100 \text{ cm})^2} \{ (0.75) (8.04) (0.8) (1 - e^{-0.693 (0.33) / 8.04}) \\ + e^{-0.693 (0.33) / 8.04} (0.25) (0.20) (0.32) \\ + e^{-0.693 (0.33) / 8.04} (0.25) (0.80) (5.2) \}$$

$$D(\infty) = 4.86 \text{ mSv (0.486 rem)}$$

Therefore, hyperthyroid patients to whom 2035 megabecquerels (55 millicuries) of iodine-131 have been administered would not have to remain under licensee control and could be released under 10 CFR 35.75 when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction $F_2 = 0.8$ is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 Internal Dose

For some radionuclides, such as iodine-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

Equation B-6:

$$D_i = Q (10^{-5})(DCF)$$

where: D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem;
 Q = Activity administered to the patient in millicuries;
 10^{-5} = Assumed fractional intake; and
 DCF = Dose conversion factor to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in Reference B-3 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered iodine-131 indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 1221 megabecquerels (33 millicuries) of iodine-131 have been administered. The ingestion pathway was selected because it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

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Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rem/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.17 \text{ mSv (0.017 rem)}$$

Using Equation B-1 and assuming the patient has received instructions for reducing exposure as recommended for an occupancy factor of 0.25, the external dose is approximately 5 mSv (0.5 rem). Thus, the internal dose is about 3% of the external dose due to gamma rays. Internal doses may be ignored in calculations of total dose if they are likely to be less than 10% of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see Reference B-1.

Example 5, Internal Dose: Calculate the maximum internal dose to a person exposed to a patient to whom 5550 megabecquerels (150 millicuries) of iodine-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, the dose is again calculated using Equation B-6 and selecting the ingestion pathway. Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.80 \text{ mSv (0.08 rem)}$$

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 3.4 millisieverts (0.34 rem), while the internal dose would be about 0.80 millisievert (0.08 rem). Thus, the internal dose is about 24% of the external gamma dose. Therefore, the internal and external doses must be summed to determine the total dose; 4.2 millisieverts (0.42 rem).

References for Supplement B

- B-1. S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, NUREG-1492, February 1997.

- B-2. K. F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.
- B-3. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^6 a Magic Number in Health Physics?')," *Health Physics*, Volume 39, Number 6, 1980.
- B-4. R. C. T. Buchanan and J. M. Brindle, "Radioiodine Therapy to Out-patients – The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970.
- B-5. A. P. Jacobson, P. A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health*, Volume 68, Number 3, 1978.
- B-6. National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Commentary No. 11, February 28, 1995.

Regulatory Analysis

"Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (NUREG-1492, February 1997) provides the regulatory basis and examines the costs and benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at NRC's Public Document Room, 2120 L Street NW, Washington, DC. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-2249), or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.



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The Honorable Edward J. Markey
U.S. House of Representatives
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Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Via e-mail to Jennifer.Berenholz@mail.house.gov

Re: Written questions for the record – Feb. 26, 2010 Hearing of the Health
Subcommittee “Medical Radiation – An Overview of the Issues”

Dear Representative Markey:

Attached please find answers to written questions submitted to the Medical
Imaging & Technology Alliance (MITA), the leading association representing the
manufacturers, innovators and developers of medical imaging and radiation
therapy systems.

If you have additional questions or require further information, please feel free to
contact me.

Sincerely,

Dave Fisher
Executive Director
Medical Imaging and Technology Alliance
703-841-3279
dfisher@medicalimaging.org

Attachment: MITA responses

1. Do you think that if a physician accidentally irradiates the wrong body part during therapeutic treatment that this should be reported as an error, to the patient, the hospital and to regulatory authorities?

Yes. Manufacturers are required to provide Medical Device Reports to FDA when an incident occurs that causes or has the potential to cause death or serious injury when the manufacturer becomes aware of the incident.

MITA encourages and is participatory in strong medical error reporting requirements. It is the responsibility of the physician to inform the patient, the hospital, and regulatory authorities.

Manufacturers should also have access to such reports to search for patterns or solutions to be used in the process of further technological innovations.

2. There are currently different reporting rules for different types of radiation-related errors that depend largely on what the source of radiation is. For example, errors related to irradiation with medical devices are reported to FDA, while the Nuclear Regulatory Commission (NRC) has authority over radiation exposure associated with radioactive materials. Do you think that if the wrong part of the body is irradiated that the rules for how this error is recorded and reported should be uniform despite the source of radiation?

Yes. MITA supports coordinated and consistent reporting of errors. All radiation has a delivery device and an operator. Therefore, all the rules should be consistent no matter what the source of radiation.

3. Do you think that for oversight and research purposes it would be helpful to have data on medical errors, such as the one described above, collected by a centralized source? If yes, who do you think that source should be? If not, why not?

Yes. MITA supports a uniform and transparent medical error reporting system.

4. What kind of information about the circumstances of a medical error should be reported and collected?

We recommend following the FDA Guidance for Medical Device Reports on what information should be collected. We also recommend a comprehensive review of existing requirements for medical error reporting with the intent of harmonizing reporting requirements across various jurisdictions.

5. Currently, requirements on patient notification after a medical error such as irradiating the wrong organ, varies widely and depends again on the source of radiation. Under what circumstances do you think that patients should be notified

of errors in their radiation procedure? Do you believe that rules about patient notification should be uniform across all States?

MITA supports uniform and transparent medical error reporting. We believe that providers have an ethical obligation to inform their patients when an error occurs.

6. How should medical error and mis-administrations be defined?

As manufacturers, we leave the definition of a medical error or mis-administration to clinicians / healthcare providers. However we believe that to maximize the usability of reported data, both the reporting requirements and the definitions of reportable events must be harmonized among individual states and jurisdictions.

7. Do you think that there should be a standardized definition and mandatory reporting framework for machine-based radiation that is consistent in every State?

See #6 above. All efforts at standardized and centralized reporting will aid in the study and future avoidance of medical errors.

8. Do you think that errors in administration should be consistently tracked by the States, independent of the source of radiation (ie. for both machine-based and nonmachine-based radiation)?

MITA supports the consistent tracking of medical errors, whether it is at the State or Federal level. We believe the rules of reporting should be consistent no matter what the source of radiation.

9. Some patients choose to go to hotels to recover rather than return home to their families. Is a physician capable of performing an individualized analysis of a hotel room that he or she has never seen to ensure that neither hotel personnel nor future room inhabitants would be exposed to unsafe levels of radiation?

As equipment manufacturers we do not have the clinical experience to determine the circumstances under which a patient may be released. Therefore, we defer to other clinical stakeholders with experience and responsibility in this area to respond. While we understand that there are applicable Federal Regulations our responsibilities or subject matter expertise as manufacturers do not include enforcement or evaluation of such regulations.

10. In this type of a release situation, how does a physician take into account exposure of hotel workers or future hotel guests who might come into contact with the radioactive sheets and other contamination that the patient leaves behind?

We refer to our response to Question 9 above. In closing we note that increasing safety can only be achieved by cooperation among clinicians, patients, device manufacturers and regulators/lawmakers.

Earley Green
Chief Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

March 31, 2010

Dear Chief Clerk Green,

It is my honor and pleasure to respond to the questions relating to my February 26th, 2010 testimony on "Medical Radiation: An Overview of the Issues." I am responding directly to three questions I have input on that were posed by the Honorable Edward J. Markey:

1. Yes, if a physician accidentally irradiates the wrong body part during a therapeutic treatment it should be reported immediately as an error to the patient, facility and regulatory authorities. Immediate medical attention should be provided the patient to mitigate any further health damage.
2. Yes, regardless of the current reporting process, future guidelines should be uniform to enhance clarity and increase the likelihood of corrective action.
3. Regarding data on radiation specific medical errors, data should be collected systematically and maintained in a central database to facilitate research preventing further instances. Most importantly, Medicalis believes point of ordering preventative action should be electronically facilitated when advanced diagnostic imaging is considered.

As my testimony indicated, we provide a web based radiology decision support and radiation safety guidance application that safeguards the patient before ionizing radiation procedures are applied. This solution measures anticipated milliSevert dosage rates and shows the physician the cumulative dosage that specific patient has encountered. We would advise strongly that clinical evidence supported and web enabled decision support should be mandated at the point of ordering to prevent over radiation before it occurs.

I hope the response to these questions is helpful and I remain entirely available to assist the Committee in any manner. Thanks for the opportunity to respond and please let me know if I can provide any more information in the future.

Respectfully,

John J. Donahue
Vice-Chairman
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